

Central Nervous System Strategy for Roche Pharmaceuticals



Presented By: Kali Jelen

Advisor: Dr. V. Seshan, Professor of Management

**Presented To: Pepperdine University Academic Year Undergraduate
Research Initiative**

December 11, 2014

To: Academic Year Undergraduate Research Initiative Committee
Pepperdine University
24255 Pacific Coast Hwy
Malibu, CA 90263

From: Kali Jelen
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Malibu, CA 90264

Re: Pepperdine Academic Year Undergraduate Research Initiative Submission

December 11, 2015

Dear Members of the Academic Year Undergraduate Research Committee,

I would like to preface my project with a brief explanation as well as to say thank you to several individuals. First and foremost thank you to Pepperdine University for encouraging undergraduate research through the Academic Year Undergraduate Research Initiative. Thank you particularly to Dr. Lee Kats and Katy Carr for administering the program.

This project stemmed from Dr. Seshan's Business Policy, Strategy and Ethics Capstone class. The topic of the project was an in depth analysis of the Swiss pharmaceutical company Roche. This project comes from the second part of the volume and has been modified to better suit this forum. I would also like to thank Dr. Seshan for his support and guidance on this endeavor.

You will notice that I have a co-author on this section, Alexander Anderson, who is a fellow Pepperdine Senior and also a member of the Capstone Class. We collaborated together on this particular segment. I would also like to thank and recognize Alex for his hard work and dedication.

Thank you again to everyone who made this program possible!

Kindest Regards,

Kali Jelen

Executive Memo

To: Academic Year Undergraduate Research Initiative Committee

From: Kali Jelen

Re: Alzheimer's Disease Strategy for Roche Pharmaceuticals

Date: December 11, 2014

Critical Issues:

Though once an industry leader in the Central Nervous System market segment, Roche Pharmaceuticals' now holds only a fraction of a percent of market share in this segment. In 2013 sales from drugs treating CNS diseases only amounted to \$865 MM, about 1.6% of Roche's total sales, falling 6% from 2012. Meanwhile the market as whole is growing rapidly. Between 2012 and 2013 the CNS market segment grew 5.75% to \$191 B. In order to retain overall Share of Market (SOM) Roche must find a way to keep up with the rapidly expanding CNS segment.

Recommended Strategy:

Roche should invest in the development of a new drug to treat Alzheimer's Disease. A treatment for this progressive, fatal Central Nervous System Disease could help Roche to regain SOM in the Central Nervous System market segment.

Justification:

Alzheimer's Disease is a progressive, fatal disease that affects 35 million people worldwide. In the next ten years the number of patients effected with Alzheimer's is expected to increase drastically as the populations of developed countries age. Furthermore, the four treatments currently approved by the FDA are only effective for half the people who take them and can only the delay the onset of the disease by at most 12 months. Finally, Roche is better suited than any of its competitors to develop a new Alzheimer's treatment thanks to the recent success of its subsidiary, Genentech's, Crenzumab technology.

Implementation Plan:

Roche has the technology to develop a vaccine for Alzheimer's. This strategy would take seven years to develop, test, and market. Roche will need to invest capital for Research and Development as well as new facilities.

Executive Summary

By: Kali Jelen

Findings- Alzheimer's Disease is a degenerative illness that causes loss of memory and motor skills, changes in personality, and eventually results in death. The disease currently affects 35 million people, worldwide, and yet no effective treatment option has yet been developed. The most prominent risk factors for the disease are age and the Apolipoprotein E4 gene. In the United States one in nine people over the age of 65 years and one in three over 85 years are suffering from Alzheimer's. Thanks to modern medicine and better living conditions, the life expectancy of people born in developed countries is increasing. In 2010 13% of the population of the United States (41 MM people) was over the age of 65. This number is forecasted to swell to 26% (approximately 90 MM people) by 2030.

Results- The rapidly aging population of the United States and other developed nations and the prevalence of Alzheimer's disease means that the market for an effective treatment option will increase greatly over the next ten years. Furthermore, Roche has lost its historical hold on the Central Nervous System Market Segment. Roche could greatly benefit from developing an effective treatment option for Alzheimer's Disease. Roche's subsidiary Genentech has been testing new technology that, thus far, has been more effective than any competitor at creating antibodies in the brain without causing dangerous swelling.

Conclusions- Roche should use the technology developed at Genentech to create a new product that will treat Alzheimer's, Aposecretase. Aposecretase will use existing technology to vaccinate against beta and gamma secretase enzymes, which are responsible for cutting the beta amyloid protein into fragments thus forming plaque which inhibits brain function. This vaccine would strengthen the body's natural antibody, microglia, to attack the enzyme and protein fragments before they begin to accumulate. This vaccine has the potential to be profitable for Roche. The company is uniquely positioned to be a first mover on this new technology and the rapidly aging population will likely provide stable demand in the years to come.

Alzheimer's Disease Strategy for Roche Pharmaceuticals

By: Alexander Anderson & Kali Jelen

Compiled By: Kali Jelen

Introduction

By: Kali Jelen

The Central Nervous System market segment is the second largest in the pharmaceutical industry, behind the Cardiovascular segment, according to Datamonitor, accounting for 19.6% of total industry sales.¹ Drugs in this market segment seek to cure diseases relating to the brain and nervous system including Depression, Epilepsy, Psychosis, and Alzheimer's disease.² The Central Nervous System market segment is growing at a rapid rate. Between 2012 and 2013 total sales increased by 5.75% to 191 billion dollars.³

Roche's sales in the Central Nervous System segment amounted to approximately 865 million dollars for 2013, down approximately 6% from 2012.⁴ Central Nervous System segment sales only accounted for about 1.6% of Roche's total 2013 sales of 52.5 billion dollars.⁵ Roche historically has been a leader in the Central Nervous segment due to their development of Valium and other sedatives. However over the past decade the company has slowly lost share to its competitors. Currently, Roche produces the drugs Dormicum, Madopar, and Valium to treat diseases of the Central Nervous System.⁶ Roche has an opportunity now to regain market share by developing drugs that specifically meet the complex needs of patients suffering from Central Nervous System diseases.

Alzheimer's disease is a progressive illness that causes problems with memory and thinking and changes in behavior and personality. It is a degenerative disease of the brain, which ultimately results in death. Alzheimer's is the single most prevalent form of *dementia* and the sixth leading cause of death in the United States.⁷ Alzheimer's primarily affects people aged 65 and older, though a small percent of people with the disease (less than 5%) are diagnosed with early onset Alzheimer's, in which symptoms manifest themselves beginning when the patient is in their 40's or 50's.⁸ Alzheimer's is a growing issue across the world, but particularly in the United States where one in nine people age 65 and older (11%) and one in three people over 85 (32%) are

suffering from the disease. In 2014 700,000 people are expected to die in the United States of Alzheimer's related causes.⁹

Exhibit 3.5.1 U.S. Annual Alzheimer's Death Rates (per 100,000) by Age

By: Kali Jelen

Age	2000	2002	2004	2006	2008	2010
45–54	0.2	0.1	0.2	0.2	0.2	0.3
55–64	2.0	1.9	1.8	2.1	2.2	2.1
65–74	18.7	19.6	19.5	19.9	21.1	19.8
75–84	139.6	157.7	168.5	175.0	192.5	184.5
85+	667.7	790.9	875.3	923.4	1,002.2	987.1
Total Death Rate*	18.1	20.8	22.6	23.7	25.8	25.1

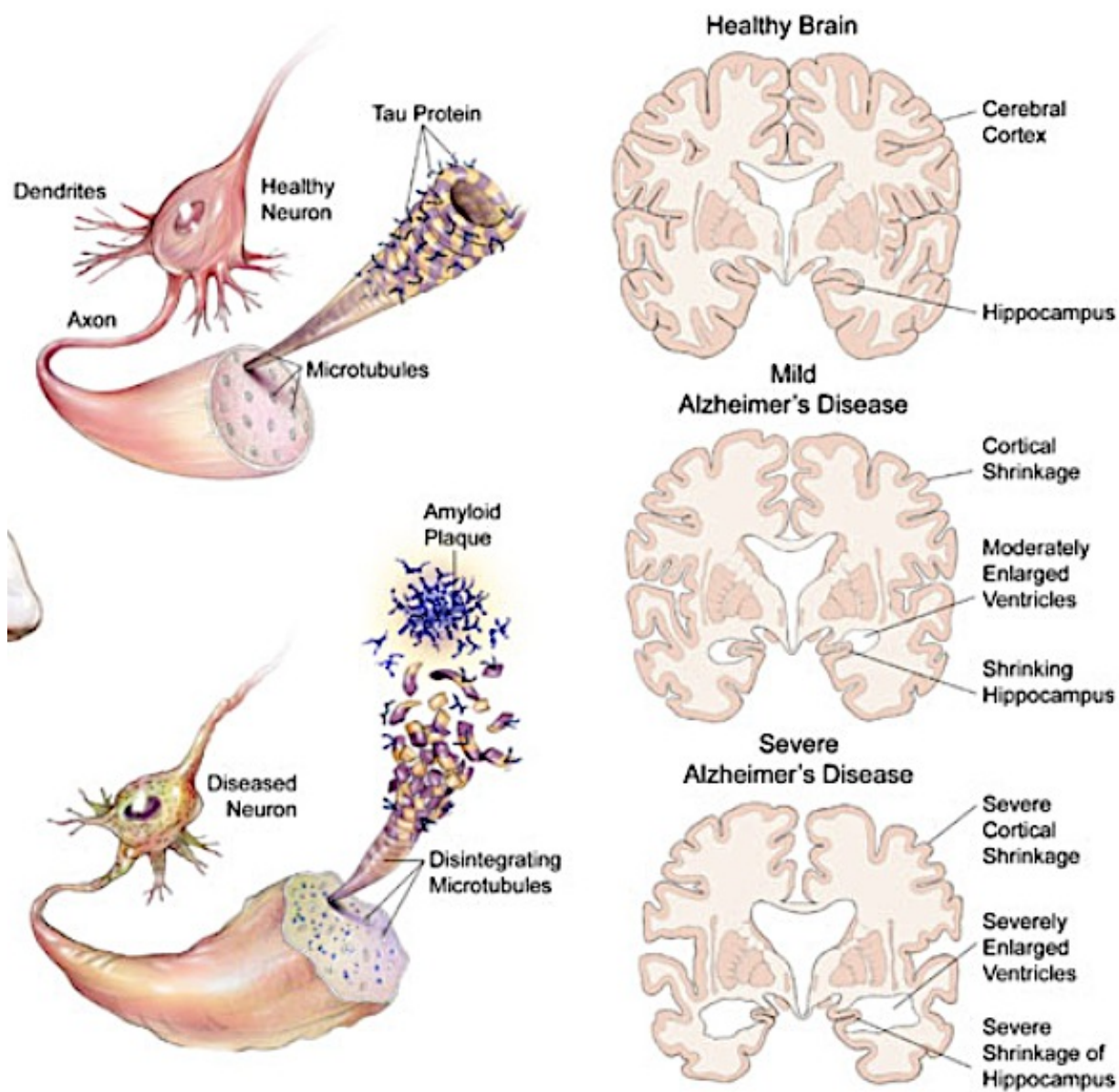
*Reflects overall death rate for ages 45 and older.

Created from data from the National Center for Health Statistics.⁽¹⁶¹⁾

Alzheimer's is caused by a build-up of beta-amyloid protein fragments that are broken off of amyloid parent proteins (APP) by two enzymes, beta secretase and gamma secretase. These proteins stick together to form oligomers.¹⁰ Over time the oligomers multiply and collectively known as plaque. All humans eventually develop a build-up of beta-amyloid protein fragments; however in Alzheimer's patients the build-up is much faster and more prominent. The number of oligomers find their way to the ends of the neurons (brain cells), which prevent synapses from firing and thus messages from being passed from one neuron to another.¹¹ The oligomers also prevent proper nutrients from reaching neurons. The tau protein is responsible for providing "tracks" in which nutrients pass over to reach the cell. The oligomers cause the tau proteins to collapse on themselves causing a tangle. These tangles prevent the neurons from getting proper nutrients.¹² There are anti-bodies in the brain, which attempt to combat the oligomers called microglia. However due to the insoluble nature of the beta amyloid protein fragments they are not very effective.¹³ In the process of attempting to kill the amyloid protein fragments the microglia cause inflammation, which exacerbates the effects of the plaque. Eventually the lack of nutrients and firing synapses cause the deterioration of each affected neuron, resulting in memory loss, confusion, personality shifts, and mobility issues in those diagnosed with the disease.¹⁴

Exhibit 3.5.2 Diagram of Plaque Affecting the Alzheimer's Brain

By: Kali Jelen

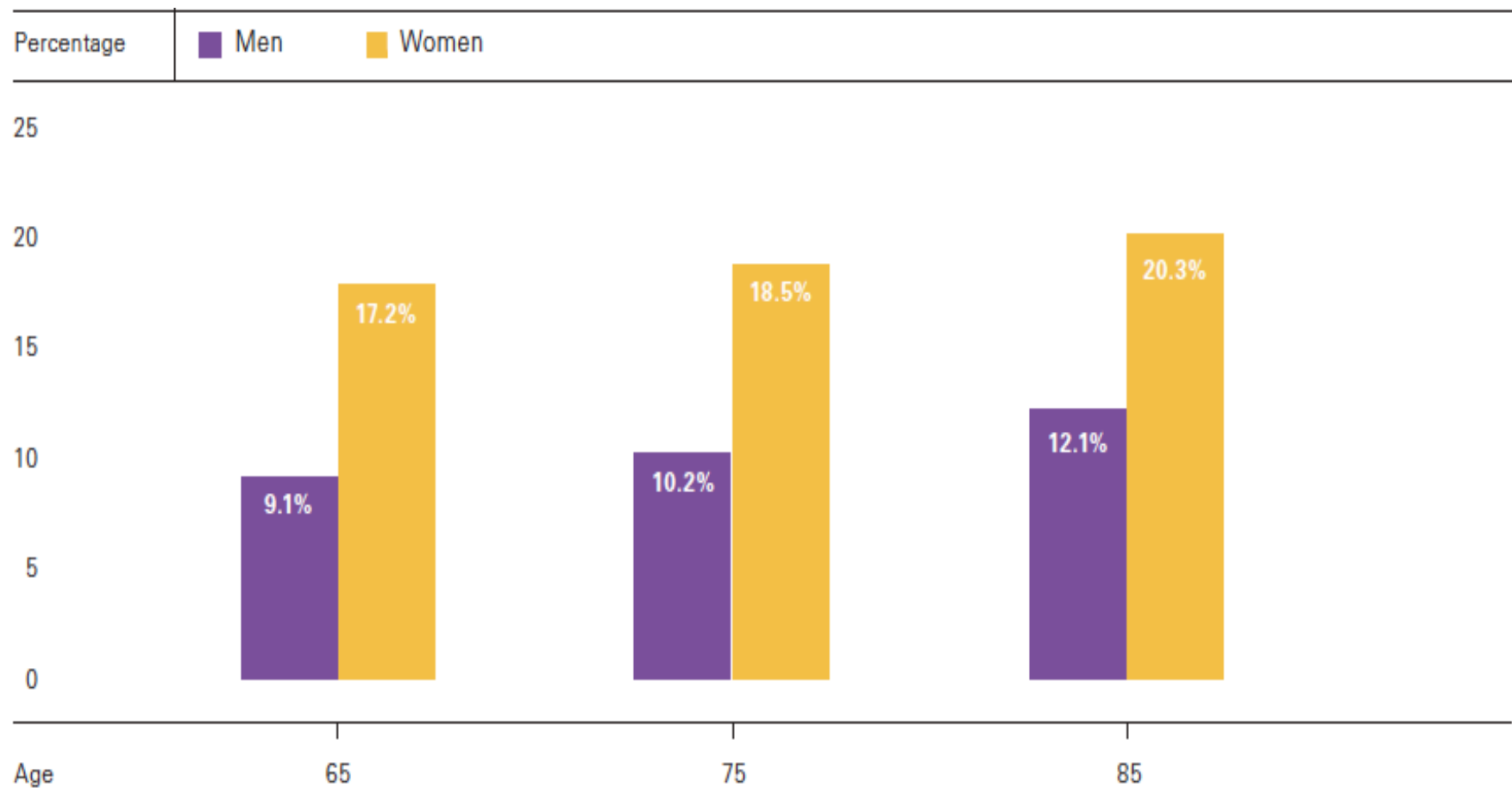


Source: "Activation of Wnt Signaling Pathway Reverses Cognitive Deficits in an Alzheimer's Disease Model." Developmental Biology Interactive. N.p., n.d. Web. 20 Oct. 2014.

The Alzheimer's Association has identified three phases of the disease: Pre-clinical, Mild Cognitive Decline, and Dementia due to Alzheimer's.¹⁵ During the first phase patients do not exhibit any symptoms, however significant brain changes begin to take place. It is impossible to diagnose at this stage. Doctors can only look at risk factors such as family history and the presence of the apolipoprotein E4 Gene to determine if the patient is likely to contract the disease.¹⁶ Phase one can last for more than twenty years. The next phase of Alzheimer's is Mild Cognitive Decline. This is the point in which patients' symptoms begin to manifest. During this stage patients will have difficulty remembering correct words and names, learning information, function in group work or social settings, remembering where things are, planning for the future, remembering personal history.¹⁷ These symptoms will worsen during the Dementia phase. Patients will begin to forget friends and family, have confusion about what day and year it is, experience a change in personality, lose awareness of surroundings, and have difficulty controlling bladder and bowels. Often during this time patients must be placed in a full time care situation. They will need assistance with daily tasks such as bathing, eating, and going to the bathroom. This final stage will continue to progress until patients lose the ability to speak and to respond to their surroundings.¹⁸ Their muscles become rigid, reflexes impair, and it becomes hard to swallow. The end of the progression is death, though often the effects of the symptoms, such as malnutrition because of the difficulty swallowing, is the actual cause of death. On average patients have only eight years to live from the start of phase one when symptoms begin to manifest themselves.¹⁹

Exhibit 3.5.3 Estimated Lifetime Risks for Alzheimer's by Age and Sex

By: Kali Jelen



Source: Latest Facts & Figures Report | Alzheimer's Association." Latest Facts & Figures Report | Alzheimer's Association. N.p., n.d. Web. 17 Oct. 2014.

Currently there is no known cure for Alzheimer's and only five drugs approved by the FDA to treat the symptoms of Alzheimer's disease. These drugs are: Aricept (donepezil), Razadyne (galantamine), Namenda (memantine), Rivastigmine (Exelon), and Cognex (Tacrine) which are produced by Eisai Ltd., Janssen (Johnson & Johnson), Forest Laboratories (Actavis), Novartis, and Pfizer, respectively.²⁰ Aricept, Rivastigmine, Razadyne, and Cognex are all *cholinesterase inhibitors* and work by preventing the breakdown of acetylcholine, an enzyme that allows messages to pass from neuron to neuron.²¹ The remaining drug Namenda works by preventing the breakdown of glutamate, a different neuron messenger and can be taken in conjunction with any of the cholinesterase inhibitors. All the five drugs have about the same success rate and can delay symptoms for 6-12 months for half of the people who take them.²² Cognex is the least popular of the medications as it comes with serious side effects such as kidney failure. It is not available in the United States at this time, but Pfizer still produces a limited amount of the drug.²³

Roche does not currently have an Alzheimer's drug on the market and therefore is missing out on a valuable opportunity. It does however, through its subsidiary Genentech, have several Alzheimer's drugs in the pipeline. None to this point have been successful though. By developing a new drug that fights the cause of Alzheimer's rather than the symptoms Roche could easily corner the market and ensure that millions of people diagnosed each year with Alzheimer's do not face a hopeless prognosis.

Critical Issues

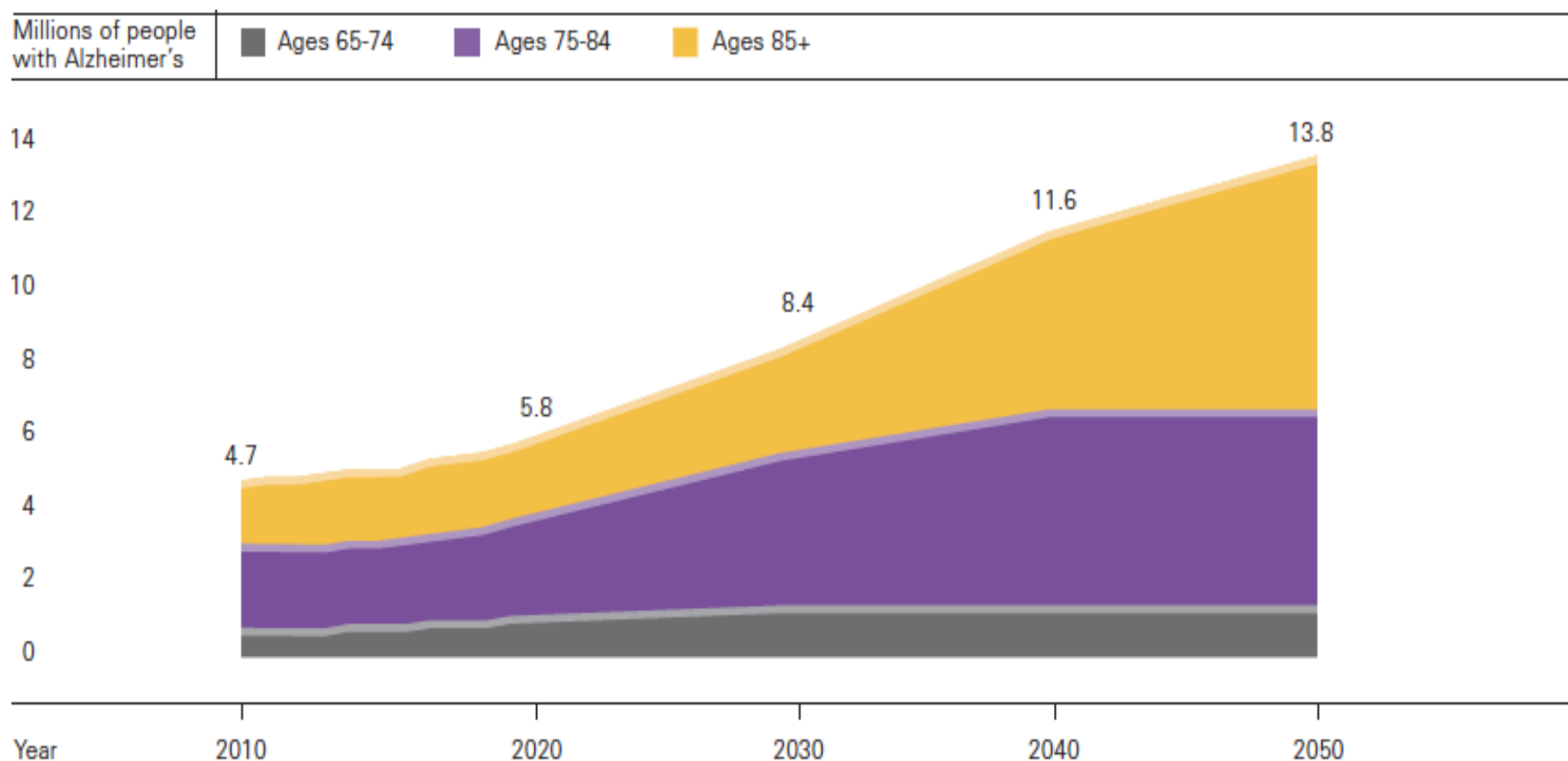
By: Kali Jelen

Currently there is a great need for a treatment that directly targets the cause of Alzheimer's disease in the Central Nervous System market segment. Thirty five million people worldwide are suffering from Alzheimer's and it affects one in nine people in the United States over the age of 65 and one in three people over the age of 85.²⁴ Currently those diagnosed with Alzheimer's face a hopeless prognosis. 100% of those diagnosed with the disease will die with the disease, usually within eight years.²⁵ In 2014, 700,000 Americans are expected to die of Alzheimer's related causes.²⁶ The situation will only get worse as the world's population ages thanks to better medical technology and more hospitable social and environmental conditions. In the United

States for instance the population over the age of 65 is expected to reach 72 million by 2030. This will account for 20% of the United States total population, up from just 13% in 2010.²⁷ Age is the single biggest risk factor for Alzheimer's disease. In 2014 an estimated 5.2 million people were suffering from Alzheimer's.²⁸

Exhibit 3.5.4 Projected Number of People Age 65 and Older with Alzheimer's in U.S. (2010-2050)

By: Kali Jelen



Source: Latest Facts & Figures Report | Alzheimer's Association." Latest Facts & Figures Report | Alzheimer's Association. N.p., n.d. Web. 17 Oct. 2014.

Because Alzheimer's treatments currently only address the symptoms of the disease and not the causes of the disease, it is necessary to begin almost from scratch and try a new approach. Roche, with the help from its' Genetech subsidiary, is in a unique position to develop a treatment option to prevent the onset and spread of Alzheimer's, rather than just addressing the symptoms. Roche could use this opportunity to make up for previous losses in the Central Nervous System market segment by recapturing its competitive advantage.

Roche and other pharmaceutical companies have been aggressively seeking to cure Alzheimer's since effective testing technology became available in the early 1990's.²⁹ None, including Roche has yet been successful. Now however, is the perfect time for Roche to redouble its efforts as many pharmaceutical companies have pulled back research and development expenditures in the CNS market segment to focus resources on other areas.³⁰ Competitors AstraZeneca, GlaxoSmithKline, Sanofi, and Merck have all but eliminated their CNS research and development pipeline, leaving plenty of room for innovation by Roche.³¹

Because of the nature of this venture the development of a completely new drug to fight Alzheimer's will require a large outlay capital for research and development and startup costs. Research programs already in place will provide a solid base for the research to build off of. However, despite the initial costs and competition, if Roche is able to achieve this goal it will have a corner on the Central Nervous System market and be able to regain market share.

Recommended Strategy

By: Kali Jelen

The recommended strategy for Roche, through Genetech, is to develop a new drug that prevents the causes of Alzheimer's. Currently, an Alzheimer's diagnosis is fatal within eight years. The five drugs approved by the FDA are not effective at preventing or reversing the disease, only in treating its symptoms. Many attempts have been made to attack the causes of Alzheimer's, however none have been totally effective. In late 2014 Genetech began clinical trials for a new Alzheimer's drug called Crenezumab. Crenezumab created a synthetic antibody to attack the beta amyloid protein fragments. At the midpoint of the study in July 2014 the project was deemed unsuccessful as the drug was not effective for a statistically significant number of patients.³² Despite the fact Crenezumab did not make it to market, it was the most successful

clinical trial thus far for medicines that seek to strengthen the body's antibodies against the plaque. Crenzumab did not cause the dangerous brain swelling seen with other Alzheimer's medications and therefore could be given in higher doses.³³

With the development of Aposecretase patients who are at risk of getting Alzheimer's will be able to get a series of vaccines, administered through a nasal inhalant, which will target the two enzymes, beta secretase and gamma secretase, that cause the beta-amaloid protein fragments to break away from the beta-amaloid parent. This process will fortify antibodies in the brain know as microglia to attack the beta secretase and gamma secretase enzymes when they begin to create the beta-amaloid protein fragment which are responsible for forming the plaque which eventually kills patients neurons. Though the Aposecretase vaccine will not reverse the effects of Alzheimer's disease, it can prevent the onset of the disease. The vaccine will be administered to all those with either one or two Apolipoprotein E4 Genes and those with a family history of Alzheimer's.

Aposecretase will be the first Alzheimer's drug to attack the enzymes responsible for the creation of the beta-amaloid protein fragments rather than the fragments themselves. Though this process will not be able to reverse the effects of Alzheimer's it will prevent more people from contracting the disease. Roche is well equipped for this task and become the first pharmaceutical company to successfully treat the cause of Alzheimer's.

Justification

By: Kali Jelen

Alzheimer's affects 35 million people across the globe and there are currently no effective treatment options.³⁴ The single biggest risk factor for Alzheimer's is age.³⁵ Thanks to modern medicine and better living conditions across the globe people are living longer. An aging world means more people will be diagnosed with Alzheimer's. For example, in the United States by 2030 20% of the population is expected to be over the age of 65. One in nine of those people will likely be diagnosed with Alzheimer's.³⁶ The need, and thus potential payoff, for an effective Alzheimer's treatment is greater now more than ever.

Roche has the technical capability to create Aposecretase. With many competitors reducing the funds for CNS research and development, now is a better time than any to actively pursue a more effective Alzheimer's treatment.

Implementation Plan

By: Kali Jelen

The development of this new Alzheimer's treatment will take approximately seven years to get to market. Those seven years will be spent researching and performing clinical trials to gain approval from governmental regulators. The initial outlay of capital for research and development will be \$1.61 B. Though Roche already has a dedicated team of researchers for the CNS market segment, more researchers and specialists will need to be brought on to help speed the process. Furthermore, new, state of the art, facilities will be needed to house the operation. After the initial research and development phase Aposecretase will undergo inspection by the FDA and other government regulators to determine that it is safe. Once the Aposecretase is deemed safe clinical trials can be conducted. First, Roche will determine the effectiveness of the drug through a double blind trial using patients in the very early stages of the disease. Assuming that the effectiveness of the drug is proven Roche will move on to larger clinical trials involving 3,000 patients or more. If Aposecretase continues to prove effective and not to have too many harmful side effects the drug will then finally be released to the market. Aposecretase will first be made available in the United States, followed by Europe, and then Japan.

Next, Roche must ramp up production to meet the needs of millions of people who are at risk of contracting Alzheimer's. Roche will use already existing production facilities in Hillsboro, Oregon repurposed to produce Aposecretase. Property, plant, and equipment dollars will be allocated to repurposing existing space and developing distribution channels. Because the manufacturing center is brand-new and state of the art, only minor changes will need to be implemented to achieve full functionality.

At this point some marketing will be necessary to promote Aposecretase to doctors and hospitals and to train in its use. Doctors need to be taught to use existing genetic testing to screen for those likely to develop Alzheimer's. Assuming the drug does not have any major side effects it will take on quickly as there are no other options for the treatment and prevention of Alzheimer's.

Product Development

By: Kali Jelen

The product development of Aposecretase will begin with an initial research and development expenditure of 1.61 billion dollars. These costs will cover the salaries of additional researchers, new equipment, and acquisition of a new facility. Since this is an entirely new venture initial costs are quite high.

After the initial research period Aposecretase will move in to the pipeline phase. An additional funds will be spend at this time to continue the research moving forward through several phases of clinical trials. This time will be used to flush out any unexpected side effects of the medication and to ensure that it is effective for most users.

Roche will then need to manufacture the drug on a larger scale, which is when it will move to Genentech's new state of the art facility in Hillsborough, Oregon. The plant, recently opened, still has available capacity to produce the new product.³⁷

Finally Roche will launch a limited marketing campaign for Aposecretase. The goal of this campaign will primarily be education of doctors and hospitals on the drug and its proper administration. Attention will also be paid to the importance of early diagnosis and the use of already established genetic testing to determine which patients are more at risk.

Research and Development Expenditures

By: Kali Jelen

The initial investment in to research and development for this project is crucial to the success of Aposecretase. The initial capital outlay will cover expenses such as the hiring of new staff and the establishment of a new laboratory and headquarters just outside of Hillsboro, Oregon. Roche will seek out the foremost neurologists and geriatric experts to join their team. Furthermore, Roche will harness its subsidiary Genentech's previous research to gain competitive advantage. Genentech's Crenezumab is the closest any pharmaceutical company has come to producing a vaccine for Alzheimer's. It is the only technology able to reach the microglia in the brain without causing dangerous swelling. Though the project has been set aside Roche will be able to use some of the advances rom Crenezumab to create Aposecretase.

Capacity Requirements

By: Kali Jelen

Roche will need labs and manufacturing facilities. In order to keep up with demand Roche will manufacture Aposecretase as the brand new state of the art plant in Hillsboro, Oregon that is set to open in 2015. The initial capital expenditure for this project will be \$1.61 B. Some of which will be used to make minor alterations to the factory in Hillsboro and the rest will go towards labs and research facilities which will be off site.

Strategic Fit

By: Kali Jelen

Roche's development of Aposecretase will fulfill an unmet need in the pharmaceutical industry. Despite the fact that Alzheimer's is the sixth biggest cause of death in the United States there are no effective, or even moderately effective treatment options.³⁸ The problem of Alzheimer's disease will only continue to grow as the population ages. Now is the perfect time to begin development of a new drug to stop the onset of this disease as the market will likely grow over the course of the next 20 years.

Growth Opportunities

By: Kali Jelen

Roche does not currently have any products on the market for the treatment of Alzheimer's. Currently there are 35 MM people in the world infected with Alzheimer's disease and no effective treatment.³⁹ The rapidly aging global population ensures that the number diagnosed will only continue to grow. Aposecretase will have extensive growth opportunities, especially in the United States and Japan where the population is aging more rapidly than the rest of the world.⁴⁰

Financial Analysis

By: Kali Jelen

Income Statement Analysis

By: Kali Jelen

An income statement is used to summarize a firm's revenue from product sales and firm's expenses over a set financial accounting period in order to determine net income. A pro-forma income statement has been created for Aposecretase for the years of 2010-2032, which covers the period from the project's inception to the expiration of the patent. The income statement covers Net Sales, Growth Rate of Sales, Cost of Goods Sold, Gross Margin, Selling Expenses, General & Administrative Expenses, Research & Development, Depreciation, Operating Expenses, Total Cost of Sales, Operating Income, Taxes, and Net Income.

Net Sales

By: Kali Jelen

Net sales (revenue) is equal to the price of the drug multiplied by units sold expressed as a dollar amount. The pricing for this drug is much higher than current Alzheimer's drugs because it will be administered as a three series inhalant vaccine, rather than a set of daily pills. Aposecretase will cost \$10 K for one individual. Meaning that each administration will be cost approximately \$3.3 K. Also, Aposecretase will do something that no other drug can, prevent Alzheimer's from progressing by killing the enzymes that make the plaque. Currently treatments are ineffective and are only effective for about half the patients who take them.⁴¹ Even then though the best possible outcome is to delay the disease by several months. The greater effectiveness of Aposecretase will justify its high price. The units sold will increase gradually each year, before leveling off when other competitor's technology catches up.

Cost of Goods Sold

By: Kali Jelen

Cost of Goods Sold describes the labor and raw materials expenditures that are made to produce a finished product. CoGS includes fixed costs and variable costs. Because no goods will be sold

for the first six years there are no CoGS during. Only after 2020 when Aposecretase hits the market is does CoGS become relevant. According to the proforma income statement Cost of Goods sold will fluctuate between 20-25% of Net Sales. Because aposecretase will develop out of the biotechnology sector the Cost of Goods sold will remain low. The Cost of Goods Sold is highest in the early years because it includes important costs such as those to establish a supply chain and distribution channels. After these initial expenditures efficiency will allow Cost of Goods Sold to decrease slightly.

Gross Margin

By: Kali Jelen

Gross Margin is the difference between Net Sales and CoGS. The Gross Margin of Aposecretase will start at \$2,975 MM in 2021 when the drug is first released and increase to \$4,107 MM during 2032, its final year before the expiration of the patent. Gross Margin will start out as 75% of Net Sales in 2021 and increase to 85% by 2032. This is due, in part, to the low Cost of Goods Sold in this industry.

Selling, General, and Administrative Expenses

By: Kali Jelen

Selling, General, and Administrative expenses cover costs such as administrator hours and marketing fees. For Aposecretase the Selling, General, and Administrative expenses will be zero until 2021 when the drug is released. From 2021-2028 the cost will be relatively high as Roche must pay for a modest advertising campaign and educational materials for hospitals and doctors who will use the drug. In 2022 Selling, General, and Administrative expensis will be 20% of Net Sales before droppin down to 10% in 2023. In 2029 though this expense will drop off off as the market becomes aware of the product and remain so until the end of the patent in 2035. From 2029 onward Selling, General, and Administrative expenses will only account for 5% of Net Sales.

Research and Development Expenditures

By: Kali Jelen

Research and Development is the single most important expenditure for all drug companies. R&D expenditures will cover researcher's salaries, laboratories, research materials, and the cost of several studies to gain governmental approval. In 2014 when the project begins total R&D expenditure will be \$120 MM. The R&D expenditure will increase at a steady rate of 5% for the useful life of the product. In 2021 when Aposecretase is released R&D Expenditure will be \$436.2 MM and account for 12% of Net Sales. By the final year of Aposecretase's patent, 2032, R&D Expenditure will equal \$746.05 MM and account for 14% of Net Sales.

It is incredibly important for Roche to keep up its R&D expenditures to avoid falling over a patent cliff. If Roche is unable to innovate a new treatment option or a variation of a current treatment option by 2032 the company will experience a major decrease in revenue.

Depreciation

By: Kali Jelen

Depreciation is an accounting tool used to represent the physical wear and tear over time on equipment and other tangible *assets*. Depreciation is listed on the pro-forma income statement as a non-cash charge. Depreciation is calculated using the useful life of property, plant, and equipment and assets' salvage value.

For Aposecretase, straight line depreciation was used to determine the depreciation schedule. Each year the depreciation expense increases until the patent expires.

Depreciation is \$76.76 MM dollars in 2014 and ends at \$175.31 MM in 2032. Depreciation accounts for approximately 3% of Net Sales throughout the life of the patent.

Earnings before Interest & Taxes (EBIT)/Operating Income

By: Kali Jelen

Earnings before interest and taxes (EBIT), also known as operating income, is calculated by subtracting Cost of Sales from net sales. Operating income is an important factor in determining the commercial success of a product. While Aposecretase is in the pipeline stages EBIT is zero.

However, when it hits the market in 2021 EBIT increases to \$1,894 MM, which is 75% of net sales. By 2026 EBIT levels off to 53% of Net Sales or \$2,224 MM and at the end of Aposecretase's patent life EBIT will account for 57% of Net Sales or \$2,929 MM.

Taxes

By: Kali Jelen

For this project Roche is taxed at a rate of 12-29%. While Aposecretase is still in the pipeline Roche is not required to pay taxes as it is operating at a loss. By 2021 though, Roche will have to pay \$1,894 MM in taxes. By the end of the drug's patent life in 2032 Roche will have to pay \$1,464 MM in taxes. The pharmaceutical industry as whole does not face an exceptionally high tax rate and therefore it is reasonable to assume that Roche will be taxed at a relatively low rate for the duration of this project.

Net Income

By: Kali Jelen

Net income is an important factor in determining the success of a given venture. It is calculated by subtracting all the production expenses, including cost of goods sold, operating expenses, and taxes from the net sales. Net income is negative while Aposecretase is in the pipeline and during the first years of sales, but becomes positive in 2021 during Aposecretase's first year of sales. In 2021 the Net Sales for this project will be \$1,894 MM. Net Income will be 27-29% of Net Sales during the life of the product. Net Sales will first be 29% in 2030 when the product has reached its full maturity.

Balance Sheet Analysis

By: Kali Jelen

The Balance sheet is a snapshot of a company's financial position at a given period of time. It details a company's assets, liabilities, and stock holder equity. The pro-forma Balance sheet below covers 21 years beginning in 2014 and ending in 2032.

Assets

By: Kali Jelen

Total assets are made up of current assets and fixed assets. Current assets are defined as those assets that will be realized within one year, while fixed assets are those non-liquids holding that cannot or will not be converted to cash in one year. Maintaining current assets is important as it indicates a company is in a position to pay off its debts. In 2014 Total Assets for this strategy will be \$1627 MM. Total Assets will increase at a fairly constant rate from 2014-2021 when Aposecretase is released. In 2021 the Total Current Assets will shoot up to \$5,351 MM. Total Assets will remain high throughout the lifetime of the strategy. Ending up in the final year of the patent (2032) at \$6,583 MM.

Liabilities

By: Kali Jelen

Like assets, Liabilities are classified in to two categories: current and long term. Current liabilities must be paid within one year while long term liabilities take longer to pay off. Liabilities include any debts the company may owe, whether short term to suppliers or long term to banks. Roche will accumulate \$3,496 MM in Total Liabilities by 2021. Though Total Liabilities will decrease over the life of the strategy, but fluctuate slightly. In 2026 Total Liabilities will be \$3,458 MM or 53% of Total Assets. By the final year of the patent in 2032 will be \$3,543 MM or 54% of Total Liabilities.

Stockholders' Equity

By: Kali Jelen

Stockholders' equity is another name for retained earnings. It is calculated by subtracting total liabilities from total assets. Assets equal liabilities plus retained earnings. In 2014 Stockholder's equity amounts to \$1,627 MM but increases as Aposecretase becomes more profitable. In 2021 Stockholder's Equity will be \$1,855 MM or 35% of Total Assets. By 2026 this number will become \$3,083 MM or 47% of Total Assets. By the final year of the Aposecretase patent Stockholder's Equity will be \$3,041 or 46% of Total Assets.

Statement of Cash Flow Analysis

By: Kali Jelen

A statement of cash flows analyzes the changes in operations, investments, and financing that alters the cash reserves of a company during a set period of time. The pro-forma statement of cash flows below covers a 21 year period from 2014 to 2034.

Permanent Investment

By: Kali Jelen

Permanent investment is the combination of property, plant, and equipment expense and research and development expenditure. It describes the long term capital investments in to the project. In 2014 the permanent Investment is \$1,920 MM. This increase steadily over the life of the strategy. By 2026 the total permanent investment has \$3,551 MM. By the end of the Pro-Forma Permant Investment Worksheet in 2035 Total Permanent Investment will have reached \$4,808 MM. Total Permanent Investment is used to calculate Working Capital.

Net working Capital

By: Kali Jelen

Net working capital is the difference between Current Assets and Current Liabilities. It is imperative to maintain net working capital in order to continue productions. Negative Change in Networking Capital indicates the liquidation of assets, thus limiting the production capabilities of an organization. For Aposecretase Working Capital will begin in 2014 at \$95 MM and grow from there. By 2021 when Aposecretase is first released Net Working Capital will be \$147 MM. By 2026 this number will have increased significantly to \$1,553 MM and by 2035 the Working Capital will have reached \$1,935 MM. The Change in Net Working Capital is consistently positive for Aposecretase.

Cash Outflow

By: Kali Jelen

Cash outflow is calculated by combining the change in permanent investment with net working capital. The cash outflow for Aposecretase is greates in 2014 at \$1,920 MM, but declines

significantly throughout the life of the patent. In 2021, the first year of sales, cash outflow will be \$151 MM. By 2026 Cash Outflow will be \$289 MM and in 2035 it will be \$157 MM. Cash Outflow is important to determining the Cumulative Cash Flow and thus the Cumulative Discounted Cash Flow which indicates the viability of a given project.

Cash Inflow

By: Kali Jelen

Cash inflow is calculated by adding depreciation to net income. Cash inflow is negative during the pipeline phase but turns around quickly as soon as the product hits the market in 2021. In 2014 Cash inflow is -\$310 MM. Cash Inflow remains negative until 2021 when it becomes \$2,013 MM. Cash inflow remains positive through the completion of the project in 2035.

Net Cash Flow

By: Kali Jelen

Net cash flow is simply the difference between cash inflow and cash outflow. It is an important part of the financial analysis because it takes in to account all prior losses and can pinpoint exactly when a project can be expected to become profitable. For Aposecretase the net cash flow will become positive in 2021 during the first year of sales.

Cumulative Net Cash Flow

By: Kali Jelen

Cumulative net cash flow is a summation of the net cash flow for all the previous years. It is a helpful measure as it describes the year in which a project reaches cash recovery. Aposecretase will meet this marker in .

Cumulative Discounted Net Cash Flow

By: Kali Jelen

The cumulative discounted net cash flow is the summation of net cash flow discounted to the year of the project's initiation, which for aposecretase is 2014. Net Cash flow is discounted at a

rate of 10% to account for inflation and the weighted average cost of capital. For Aposecretase the strategy cumulative discounted net cash flow is negative until year end 2023.

Exhibit 3.5.5 21 Yr. Net Sales Forecast \$MM- Company: Roche- Aposecretase (2014-2032)

By: Kali Jelen

Year	Total Units Sold	Price	Sales (\$MM)	Growth Rate	Cumulative (\$MM)
2014	-	-	-	-	-
2015	-	-	-	-	-
2016	-	-	-	-	-
2017	-	-	-	-	-
2018	-	-	-	-	-
2019	-	-	-	-	-
2020	-	-	-	-	-
2021	350000	10000	\$ 3,500.00	-	3,500.00
2022	360500	10000	\$ 3,605.00	3.00%	7,105.00
2023	374920	10000	\$ 3,749.20	4.00%	10,854.20
2024	386167.6	10000	\$ 3,861.68	3.00%	14,715.88
2025	401614.304	10000	\$ 4,016.14	4.00%	18,732.02
2026	417678.876	10000	\$ 4,176.79	4.00%	22,908.81
2027	434386.031	10000	\$ 4,343.86	4.00%	27,252.67
2028	451761.472	10000	\$ 4,517.61	4.00%	31,770.28
2029	465314.317	10000	\$ 4,653.14	3.00%	36,423.43
2030	483926.889	10000	\$ 4,839.27	4.00%	41,262.69
2031	498444.696	10000	\$ 4,984.45	3.00%	46,247.14
2032	513398.037	10000	\$ 5,133.98	3.00%	51,381.12
2033	523665.998	10000	\$ 5,236.66	2.00%	56,617.78
2034	539375.978	10000	\$ 5,393.76	3.00%	62,011.54
2035	550163.497	10000	\$ 5,501.63	2.00%	67,513.18

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.6 21 Yr. 30 Yr. Depreciation Schedule \$MM- Company: Roche - Aposecretase (2014-2025)

By: Kali Jelen

Calc. of Init. Strat. Cap. Expend.	
Initial Capital Expenditure 2004 (\$MM)	1,610
Useful Life of Capital	21 Years

Add. Cap. Expend.	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Property, Plant and Equipment	1,610	1,771	1,930	2,085	2,210	2,320	2,413	2,510	2,585	2,688	2,769	2,880
Growth Percent of Capital Expenditures		10%	9%	8%	6%	5%	4%	4%	3%	4%	3%	4%
Additional Capital Expenditures		161	159	154	125	110	93	97	75	103	81	111
Dep. on Add. Cap. Expend. Outlay	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Depreciation on Additional Capital Expenditures	-	-	-	-	-	-	-	-	-	-	-	-
		7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67
			7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59
				7.35	7.35	7.35	7.35	7.35	7.35	7.35	7.35	7.35
					5.96	5.96	5.96	5.96	5.96	5.96	5.96	5.96
						5.26	5.26	5.26	5.26	5.26	5.26	5.26
							4.42	4.42	4.42	4.42	4.42	4.42
								4.60	4.60	4.60	4.60	4.60
									3.59	3.59	3.59	3.59
										4.92	4.92	4.92
											3.84	3.84
												5.27
Depreciation on Additional Capital Expenditures	-	7.67	15.26	22.61	28.57	33.83	38.25	42.85	46.43	51.35	55.20	60.47
Depreciation on Initial Strategic Outlay	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67
Total Depreciation (To I.S. & C.F.)	76.67	84.33	91.92	99.28	105.23	110.50	114.92	119.51	123.10	128.02	131.86	137.14
Total Strategic Property, Plant and Equipment	1,610	1,771	1,930	2,085	2,210	2,320	2,413	2,510	2,585	2,688	2,769	2,880
Accumulated Depreciation on Strategy P,P&E to B.S.	76.67	161.00	252.92	352.20	457.43	567.93	682.85	802.36	925.45	1,053.48	1,185.34	1,322.47
Net Property, Plant and Equipment	1533.33	1610.00	1677.47	1,732.62	1,752.48	1,752.48	1,730.38	1,707.39	1,659.59	1,634.97	1,583.76	1,557.39

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.7 21 Yr. 30 Yr. Depreciation Schedule \$MM- Company: Roche - Aposecretase (2026-2035)

By: Kali Jelen

<i>\$MM</i>										
Add. Cap. Expend.	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Property, Plant and Equipment	2,995	3,115	3,239	3,337	3,470	3,574	3,681	3,755	3,868	3,945
Growth Percent of Capital Expenditures	4%	4%	4%	3%	4%	3%	3%	2%	3%	2%
Additional Capital Expenditures	115	120	125	97	133	104	107	74	113	77
Dep. on Add. Cap. Expend. Outlay	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Depreciation on Additional Capital Expenditures	-	-	-	-	-	-	-	-	-	-
	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67	7.67
	7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59	7.59
	7.35	7.35	7.35	7.35	7.35	7.35	7.35	7.35	7.35	7.35
	5.96	5.96	5.96	5.96	5.96	5.96	5.96	5.96	5.96	5.96
	5.26	5.26	5.26	5.26	5.26	5.26	5.26	5.26	5.26	5.26
	4.42	4.42	4.42	4.42	4.42	4.42	4.42	4.42	4.42	4.42
	4.60	4.60	4.60	4.60	4.60	4.60	4.60	4.60	4.60	4.60
	3.59	3.59	3.59	3.59	3.59	3.59	3.59	3.59	3.59	3.59
	4.92	4.92	4.92	4.92	4.92	4.92	4.92	4.92	4.92	4.92
	3.84	3.84	3.84	3.84	3.84	3.84	3.84	3.84	3.84	3.84
	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27	5.27
	5.49	5.49	5.49	5.49	5.49	5.49	5.49	5.49	5.49	5.49
		5.70	5.70	5.70	5.70	5.70	5.70	5.70	5.70	5.70
			5.93	5.93	5.93	5.93	5.93	5.93	5.93	5.93
				4.63	4.63	4.63	4.63	4.63	4.63	4.63
					6.36	6.36	6.36	6.36	6.36	6.36
						4.96	4.96	4.96	4.96	4.96
							5.11	5.11	5.11	5.11
								3.51	3.51	3.51
									5.36	5.36
										3.68
Depreciation on Additional Capital Expenditures	65.96	71.66	77.59	82.22	88.58	93.53	98.64	102.15	107.51	111.19
Depreciation on Initial Strategic Outlay	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	76.67	-
Total Depreciation	142.62	148.33	154.26	158.89	165.24	170.20	175.31	178.81	184.18	111.19
Total Strategic Property, Plant and Equipment	2,995	3,115	3,239	3,337	3,470	3,574	3,681	3,755	3,868	3,945
Accumulated Depreciation on Strategic P,P&E	1,465	1,613	1,768	1,927	2,092	2,262	2,437	2,616	2,800	2,912
Net Property, Plant and Equipment	1,529.96	1,501.44	1,471.77	1,410.07	1,378.29	1,312.19	1,244.11	1,138.93	1,067.40	1,033.57

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013

Exhibit 3.5.8 21 Yr. 21 Yr. Pro-Forma Income Statements \$MM- Company: Roche - Aposecretase (2014-2019)

By: Kali Jelen

<i>\$MM</i>	2014	% of Sales	2015	% of Sales	2016	% of Sales	2017	% of Sales	2018	% of Sales	2019	% of Sales
Growth Rate												
Net Sales	-	0%	-	0%	-	0%	-	0%	-	0%	-	0
COGS	-	0%	-	0%	-	0%	-	0%	-	0%	-	0
Gross Margin	-	0%	-	0%	-	0%	-	0%	-	0%	-	0
<i>Additional Capital Expenditures for capacity growth to support Net Sales</i>												
S,G&A		0%	-	0%	-	0%	-	0%	-	0%	-	0
R&D	310.00	0%	325.50	0%	341.78	0%	358.86	0%	376.81	0%	395.65	0
Depreciation Expense	76.67	0%	84.33	0%	91.92	0%	99.28	0%	105.23	0%	110.50	0
Operating Expenses	386.67	0%	409.83	0%	433.70	0%	458.14	0%	482.04	0%	506.14	0
(TCOS) Total Cost of Sales	386.67	0%	409.83	0%	433.70	0%	458.14	0%	482.04	0%	506.14	0
Operating Income (EBIT)	(386.67)	0%	(409.83)	0%	(433.70)	0%	(458.14)	0%	(482.04)	0%	(506.14)	0
Taxes	0	0%		0%	-	0%	-	0%	-	0%	-	0
Net Income	(386.67)	0%	(409.83)	0%	(433.70)	0%	(458.14)	0%	(482.04)	0%	(506.14)	0

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.9 21 Yr. 21 Yr. Pro-Forma Income Statement \$MM- Company: Roche - Aposecretase (2020-2025)

By: Kali Jelen

\$MM	2020	% of Sales	2021	% of Sales	2022	% of Sales	2023	% of Sales	2024	% of Sales	2025	% of Sales
Growth Rate					3%		4%		3%		4%	
Net Sales	-	0%	3,500.00	100%	3,605.00	100%	3,749.20	100%	3,861.68	100%	4,016.14	100%
COGS	-	0%	875.00	25%	901.25	25%	749.84	20%	772.34	20%	923.71	23%
Gross Margin	-	0%	2,625.00	75%	2,703.75	75%	2,999.36	80%	3,089.34	80%	3,092.43	77%
<i>Additional Capital Expenditures for capacity growth to support Net Sales</i>												
S,G&A	-	0%	175.00	5%	721.00	20%	374.92	10%	386.17	10%	401.61	10%
R&D	415.43	0%	436.20	12%	458.01	13%	480.91	13%	504.96	13%	530.21	13%
Depreciation Expense	114.92	0%	119.51	3%	123.10	3%	128.02	3%	131.86	3%		0%
Operating Expenses	530.34	0%	730.71	0%	1,302.11	36%	983.85	26%	1,022.99	26%	931.82	23%
(TCOS) Total Cost of Sales	530.34	0%	1,605.71	25%	2,203.36	61%	1,733.69	46%	1,795.32	46%	1,855.53	46%
Operating Income (EBIT)	(530.34)	0%	1,894.29	75%	1,401.64	39%	2,015.51	54%	2,066.35	54%	2,160.61	54%
Taxes	-	0%	-	0%	420.49	12%	1,007.75	27%	1,033.18	27%	1,080.31	16%
Net Income	(530.34)	0%	1,894.29	0%	981.15	27%	1,007.75	27%	1,033.18	27%	1,080.31	27%

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.10 21 Yr. 21 Yr. Pro-Forma Income Statement \$MM- Company: Roche - Aposecretase (2026-2032)

By: Kali Jelen

\$MM	2026	% of Sales	2027	% of Sales	2028	% of Sales	2029	% of Sales	2030	% of Sales	2031	% of Sales	2032
Growth Rate	4%		4%		4%		3%		4%		3%		3%
Net Sales	4,176.79	100%	4,343.86	100%	4,517.61	100%	4,653.14	100%	4,839.27	100%	4,984.45	100%	5,133.98
COGS	835.36	20%	868.77	20%	903.52	20%	930.63	20%	967.85	20%	996.89	20%	1,026.80
Gross Margin	3,341.43	80%	3,475.09	80%	3,614.09	80%	3,722.51	80%	3,871.42	80%	3,987.56	80%	4,107.18
<i>Additional Capital Expenditures for capacity growth to support Net Sales</i>													
S,G&A	417.68	10%	434.39	10%	451.76	10%	232.66	5%	241.96	5%	249.22	5%	256.70
R&D	556.72	13%	584.55	13%	613.78	14%	644.47	14%	676.69	14%	710.53	14%	746.05
Depreciation Expense	142.62	3%	148.33	3%	154.26	3%	158.89	3%	165.24	3%	170.20	3%	175.31
Operating Expenses	1,117.02	27%	1,167.26	27%	1,219.80	27%	1,036.01	22%	1,083.90	22%	1,129.95	23%	1,178.06
(TCOS) Total Cost of Sales	1,952.37	47%	2,036.04	47%	2,123.32	47%	1,966.64	42%	2,051.75	42%	2,126.84	43%	2,204.85
Operating Income (EBIT)	2,224.41	53%	2,307.82	53%	2,394.29	53%	2,686.50	58%	2,787.52	58%	2,857.61	57%	2,929.13
Taxes	1,112.21	27%	1,153.91	27%	1,197.15	26%	1,343.25	29%	1,393.76	29%	1,428.80	29%	1,464.56
Net Income	1,112.21	27%	1,153.91	27%	1,197.15	26%	1,343.25	29%	1,393.76	29%	1,428.80	29%	1,464.56

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.11 21 Yr. 21 Yr. Pro-Forma Balance Sheet \$MM- Company: Roche - Aposecretase (2014-2019)

By: Kali Jelen

Item	2014	%TA	2015	%TA	2016	%TA	2017	%TA	2018	%TA	2019	%TA
\$MM Assets												
Current Assets:												
Cash	94.10	6%	96.36	6%	98.99	6%	101.72	6%	104.53	6%	106.01	6%
Accounts Receivables	-	0%	-	0%	-	0%	-	0%	-	0%	-	0%
Inventories	-	0%	-	0%	-	0%	-	0%	-	0%	-	0%
Total Current Assets	94.10	6%	96.36	6%	98.99	6%	101.72	6%	104.53	6%	106.01	6%
Property, Plant & Equipment	1610	99%	1,771.00	104%	1,930.39	109%	2,084.82	114%	2,209.91	0%	2,320.41	125%
Less: Accumulated Depreciation	76.667	5%	161.00	9%	252.92	14%	352.20	19%	457.43	25%	567.93	31%
Net P,P & E Assets:	1533.3	94%	1,610.00	94%	1,677.47	94%	1,732.62	94%	1,752.48	94%	1,752.48	94%
Total Assets	1627.4	100%	1,706.36	100%	1,776.46	100%	1,834.34	100%	1,857.01	100%	1,858.49	100%
Liabilities												
Current Liabilities:												
Accounts Payable	-	0%	-	0%		0%		0%		0%		0%
Other Liabilities	-	0%		0%		0%		0%		0%	-	0%
Total Current Liabilities:	-	0%	-	0%	-	0%	-	0%	-	0%	-	0%
Net Working Capital (NWC)	94.10	6%	96.36	6%	98.99	6%	101.72	6%	104.53	6%	106.01	6%
Long-Term Liabilities:												
Long-Term Debt	-	0%	-	0%	-	0%	-	0%	-	0%	-	0%
Total Liabilities	-	0%	-	0%	-	0%	-	0%	-	0%	-	0%
Stockholders Equity												
Stockholders Equity:												
Retained Earnings from Strategy	1627.4	100%	1,706.36	100%	1,776.46	100%	1,834.34	100%	1,857.01	100%	1,858.49	100%
Total Stockholders Equity	1627.4	100%	1,706.36	100%	1,776.46	100%	1,834.34	100%	1,857.01	100%	1,858.49	100%
Total Liabilities & Stockhldr Equity:	1627.4	100%	1,706.36	100%	1,776.46	100%	1,834.34	100%	1,857.01	100%	1,858.49	100%

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.12 21 Yr. 21 Yr. Pro-Forma Balance Sheet \$MM- Company: Roche - Aposecretase (2020-2025)

By: Kali Jelen

Item	2020	%TA	2021	%TA	2022	%TA	2023	%TA	2024	%TA	2025	%TA
Assets												
Current Assets:												
Cash	112.61	6%	4.12	0%	-	0%	-	0%	-	0%	-	0%
Accounts Receivable \$MM	-	0%	1,540.00	29%	1,586.20	31%	1,499.68	32%	1,699.14	30%	1,767.10	31%
Inventories	6.00	0%	2,100.00	39%	1,802.50	36%	1,499.68	32%	2,317.01	41%	2,409.69	42%
Total Current Assets	118.61	6%	3,644.12	68%	3,388.70	67%	2,999.36	65%	4,016.14	72%	4,176.79	73%
Property, Plant & Equipment	2,413.22	131%	2,509.75	47%	2,585.04	51%	2,688.45	58%	2,769.10	49%	2,879.86	50%
Less: Accumulated Depreciation	682.85	37%	802.36	15%	925.45	18%	1,053.48	23%	1,185.34	21%	1,322.47	23%
Net P,P & E Assets:	1,730.38	94%	1,707.39	32%	1,659.59	33%	1,634.97	35%	1,583.76	28%	1,557.39	27%
Total Assets	1,848.98	100%	5,351.52	100%	5,048.29	100%	4,634.33	100%	5,599.90	100%	5,734.18	100%
Liabilities												
Current Liabilities:												
Accounts Payable	2.10	0%	1,295.00	24%	1,081.50	21%	749.84	16%	1,158.50	21%	1,204.84	21%
Other Liabilities	3.42	0%	2,201.50	41%	1,838.55	36%	1,274.73	28%	1,540.81	28%	1,566.30	27%
Total Current Liabilities:	5.52	0%	3,496.50	65%	2,920.05	58%	2,024.57	44%	2,699.31	48%	2,771.14	48%
Net Working Capital (NWC)	113.08	6%	147.62	3%	468.65	9%	974.79	21%	1,316.83	24%	1,405.65	25%
Long-Term Liabilities:												
Long-Term Debt	-	-	-	-	-	-	-	-	-	-	-	-
Total Liabilities	5.52	0%	3,496.50	65%	2,920.05	58%	2,024.57	44%	2,699.31	48%	2,771.14	48%
Stockholders Equity												
Stockholders Equity:												
Retained Earnings from Strategy	1,843.46	100%	1,855.02	35%	2,128.24	42%	2,609.76	56%	2,900.59	52%	2,963.04	52%
Total Stockholders Equity	1,843.46	100%	1,855.02	35%	2,128.24	42%	2,609.76	56%	2,900.59	52%	2,963.04	52%
Total Liabilities & Stockhldr Equity:	1,848.98	100%	5,351.52	100%	5,048.29	100%	4,634.33	100%	5,599.90	100%	5,734.18	100%

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.13 21 Yr. 21 Yr. Pro-Forma Balance Sheet \$MM- Company: Roche - Aposecretase (2026-2032)

By: Kali Jelen

Item	2026	%TA	2027	%TA	2028	%TA	2029	%TA	2030	%TA	2031	%TA	2032	%TA
Assets														
Current Assets:														
Cash	668.29	10%	695.02	10%	722.82	10%	744.50	11%	774.28	11%	0.00	0%	0.00	0%
Accounts Receivable	1,837.79	28%	1,911.30	28%	1,987.75	29%	2,047.38	29%	2,129.28	30%	2193.16	34%	2258.95	34%
Inventories	2,506.07	38%	2,606.32	39%	2,710.57	39%	2,791.89	40%	2,903.56	40%	2990.67	46%	3080.39	47%
Total Current Assets	5,012.15	77%	5,212.63	78%	5,421.14	79%	5,583.77	80%	5,807.12	81%	5183.82	0.80	5339.34	81%
Property, Plant & Equipment	2,995.06	46%	3,114.86	46%	3,239.45	47%	3,336.64	48%	3,470.10	48%	3574.21	0.55	3681.43	56%
Less: Accumulated Depreciation	1,465.10	22%	1,613.42	24%	1,767.68	26%	1,926.57	28%	2,091.81	29%	2262.01	0.35	2437.32	37%
Net P,P & E Assets:	1,529.96	23%	1,501.44	22%	1,471.77	21%	1,410.07	20%	1,378.29	19%	1312.19	0.20	1244.11	19%
Total Assets	6,542.11	100%	6,714.07	100%	6,892.91	100%	6,993.84	100%	7,185.41	100%	6496.02	1.00	6583.45	100%
Liabilities														
Current Liabilities:														
Accounts Payable	1,503.64	23%	1,563.79	23%	1,626.34	24%	1,675.13	24%	1,742.14	24%	1485.37	23%	1540.19	23%
Other Liabilities	1,954.74	30%	2,032.93	30%	2,114.24	31%	2,177.67	31%	2,317.04	32%	1930.97	30%	2002.25	30%
Total Current Liabilities:	3,458.38	53%	3,596.72	54%	3,740.58	54%	3,852.80	55%	4,059.18	56%	3416.34	0.53	3542.45	54%
Net Working Capital (NWC)	1,553.77	24%	1,615.92	24%	1,680.55	24%	1,730.97	25%	1,747.94	24%	1767.48	0.27	1796.89	27%
Long-Term Liabilities:														
Long-Term Debt	-	-	-	-	-	-	-	-	-	-	0.00	0.00	0.00	-
Total Liabilities	3,458.38	0.53	3,596.72	0.54	3,740.58	0.54	3,852.80	0.55	4,059.18	0.56	3416.34	0.53	3542.45	54%
Stockholders Equity														
Stockholders Equity:														
Retained Earnings from Strategy	3,083.73	47%	3,117.35	46%	3,152.32	46%	3,141.04	45%	3,126.23	44%	3079.68	0.47	3041.01	46%
Total Stockholders Equity	3,083.73	47%	3,117.35	46%	3,152.32	46%	3,141.04	45%	3,126.23	44%	3079.68	0.47	3041.01	46%
Total Liabilities & StockHldr Equity:	6,542.11	100%	6,714.07	100%	6,892.91	100%	6,993.84	100%	7,185.41	100%	6496.02	1.00	6583.45	100%

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.14 21 Yr. 21 Yr. Schedule of R&D Expenditures \$MM- Company: Roche - Aposecretase (2014-2032)

By: Kali Jelen

Year	Expenditures for R&D (\$MM)	Percentage Change	R&D as % of Net Sales
2014	\$ 310.00		0%
2015	\$ 325.50	5%	0%
2016	\$ 341.78	5%	0%
2017	\$ 358.86	5%	0%
2018	\$ 376.81	5%	0%
2019	\$ 395.65	5%	0%
2020	\$ 415.43	5%	0%
2021	\$ 436.20	5%	12.46%
2022	\$ 458.01	5%	12.70%
2023	\$ 480.91	5%	12.83%
2024	\$ 504.96	5%	13.08%
2025	\$ 530.21	5%	13.20%
2026	\$ 556.72	5%	13.33%
2027	\$ 584.55	5%	13.46%
2028	\$ 613.78	5%	13.59%
2029	\$ 644.47	5%	13.85%
2030	\$ 676.69	5%	13.98%
2031	\$ 710.53	5%	14.25%
2032	\$ 746.05	5%	14.53%
2033	\$ 783.35	5%	14.96%
2034	\$ 822.52	5%	15.25%
2035	\$ 863.65	5%	15.70%

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.15 21 Yr. 21 Permanent Investment Worksheet \$MM- Company: Roche - Aposecretase (2014-2032)

By: Kali Jelen

Year	Net Sales \$MM	Property, Plant & Equipment	R & D	Total Permanent Investment	Change in Permanent Investment	Working Capital	Change in Working Capital
2014	-	1610.00	310.00	1920.00	1920.00	94	94
2015	-	1771.00	325.50	2096.50	176.50	96.36	2.26
2016	-	1930.39	341.78	2272.17	175.67	98.99	2.64
2017	-	2084.82	358.86	2443.68	171.52	101.72	2.72
2018	-	2209.91	376.81	2586.72	143.03	104.53	2.82
2019	-	2320.41	395.65	2716.05	129.34	106.01	1.48
2020	-	2413.22	415.43	2828.65	112.60	113.08	7.07
2021	3,500.00	2509.75	436.20	2945.95	117.30	147.62	34.54
2022	3,605.00	2585.04	458.01	3043.05	97.10	468.65	321.03
2023	3,749.20	2688.45	480.91	3169.36	126.30	974.79	506.14
2024	3,861.68	2769.10	504.96	3274.06	104.70	1316.83	342.04
2025	4,016.14	2879.86	530.21	3410.07	136.01	1405.65	88.82
2026	4,176.79	2995.06	556.72	3551.77	141.70	1553.77	148.12
2027	4,343.86	3114.86	584.55	3699.41	147.64	1615.92	62.15
2028	4,517.61	3239.45	613.78	3853.23	153.82	1680.55	64.64
2029	4,653.14	3336.64	644.47	3981.11	127.87	1730.97	50.42
2030	4,839.27	3470.10	676.69	4146.79	165.69	1747.94	16.97
2031	4,984.45	3574.21	710.53	4284.73	137.94	1767.48	19.54
2032	5,133.98	3681.43	746.05	4427.48	142.75	1796.89	29.41
2033	5,236.66	3755.06	783.35	4538.42	110.93	1832.83	35.94
2034	5,393.76	3867.71	822.52	4690.24	151.82	1897.80	64.97
2035	5,501.63	3945.07	863.65	4808.72	118.48	1936.36	38.56

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.16 21 Yr. 21 Cash Flow Projections \$MM- Company: Roche - Aposecretase (2014-2032)

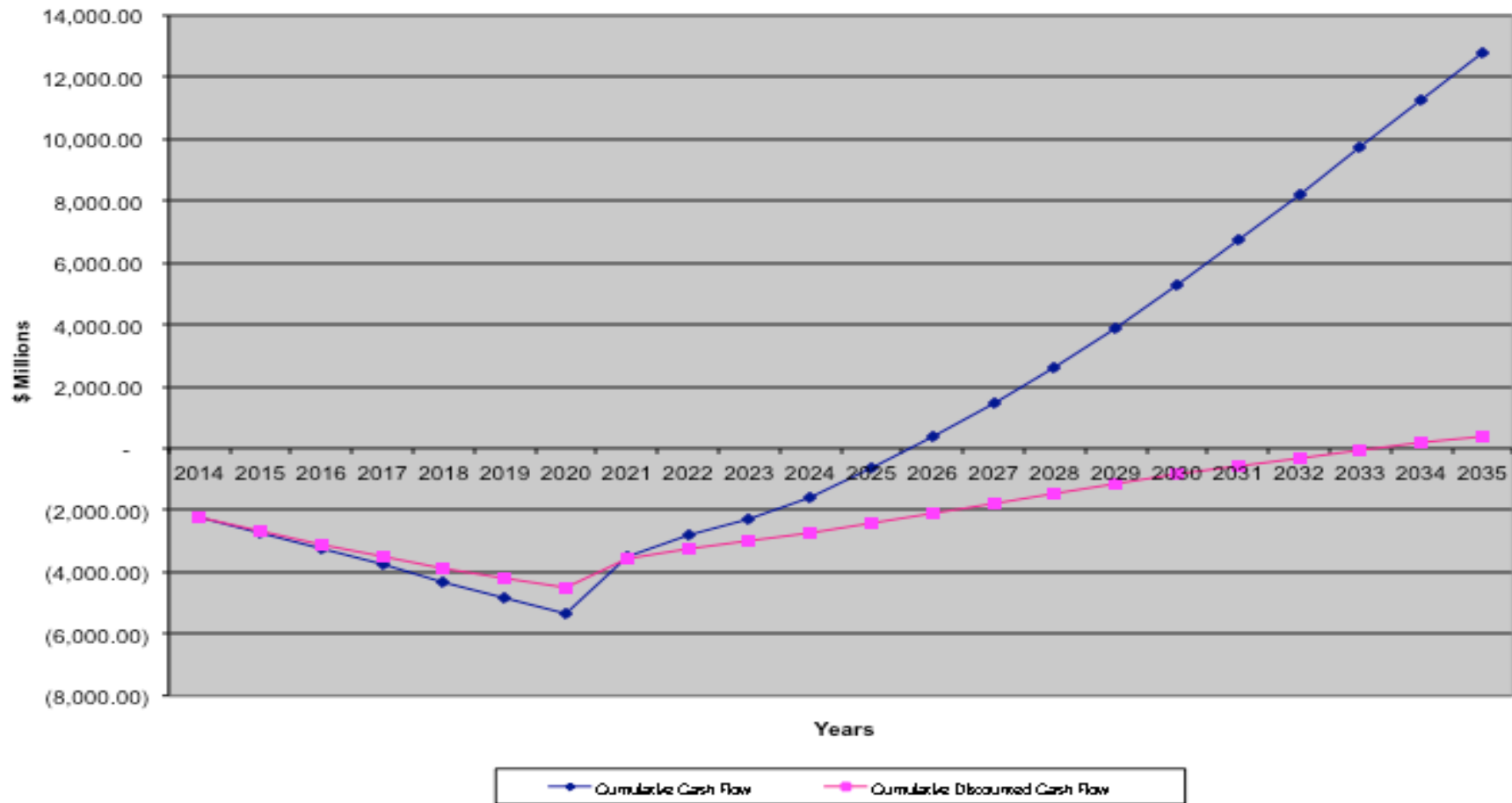
By: Kali Jelen

Year	Change in Permanent Investment	Change in Net Working Capital	Cash Outflow	Depreciation	Net Income	Cash Inflow	Net Cash Flow	Cumulative Cash Flow	Discounted Net Cash Flow @ 10%	Cumulative Discounted Cash Flow @ 10%
	P,P&E+R&D	(NWC)2 - (NWC)1 Change in NWC	(Change in Permanent Investment + Change in Net Working Capital)	(Straight-Line)		(Depreciation + Net Income)	(Cash Inflow- Cash Outflow)			
2014	1920.00		1,920.00	76.67	(386.67)	(310.00)	(2,230.00)	(2,230.00)	(2,230.00)	(2,230.00)
2015	176.50	2.26	178.76	84.33	(409.83)	(325.50)	(504.26)	(2,734.26)	(458.42)	(2,688.42)
2016	175.67	2.64	178.30	91.92	(433.70)	(341.78)	(520.08)	(3,254.33)	(429.81)	(3,118.23)
2017	171.52	2.72	174.24	99.28	(458.14)	(358.86)	(533.11)	(3,787.44)	(400.53)	(3,518.76)
2018	143.03	2.82	145.85	105.23	(482.04)	(376.81)	(522.66)	(4,310.10)	(356.98)	(3,875.74)
2019	129.34	1.48	130.82	110.50	(506.14)	(395.65)	(526.46)	(4,836.56)	(326.89)	(4,202.63)
2020	112.60	7.07	119.67	114.92	(530.34)	(415.43)	(535.10)	(5,371.66)	(302.05)	(4,504.68)
2021	117.30	34.54	151.84	119.51	1,894.29	2,013.80	1,861.96	(3,509.70)	955.48	(3,549.20)
2022	97.10	321.03	418.13	123.10	981.15	1,104.25	686.12	(2,823.58)	320.08	(3,229.13)
2023	126.30	506.14	632.44	128.02	1,007.75	1,135.77	503.33	(2,320.25)	213.46	(3,015.66)
2024	104.70	342.04	446.74	131.86	1,033.18	1,165.04	718.30	(1,601.95)	276.94	(2,738.73)
2025	136.01	88.82	224.83	137.14	1,080.31	1,217.44	992.61	(609.34)	347.90	(2,390.82)
2026	141.70	148.12	289.82	142.62	1,112.21	1,254.83	965.01	355.67	307.48	(2,083.34)
2027	147.64	62.15	209.79	148.33	1,153.91	1,302.24	1,092.45	1,448.12	316.44	(1,766.90)
2028	153.82	64.64	218.46	154.26	1,197.15	1,351.41	1,132.95	2,581.07	298.34	(1,468.56)
2029	127.87	50.42	178.29	158.89	1,343.25	1,502.14	1,323.85	3,904.92	316.92	(1,151.64)
2030	165.69	16.97	182.66	165.24	1,393.76	1,559.00	1,376.34	5,281.25	299.53	(852.11)
2031	137.94	19.54	157.48	170.20	1,428.80	1,599.00	1,441.53	6,722.78	285.20	(566.91)
2032	142.75	29.41	172.16	175.31	1,464.56	1,639.87	1,467.71	8,190.49	263.98	(302.93)
2033	110.93	35.94	146.87	178.81	1,508.85	1,687.66	1,540.79	9,731.28	251.93	(51.00)
2034	151.82	64.97	216.79	184.18	1,546.28	1,730.46	1,513.67	11,244.95	225.00	174.00
2035	118.48	38.56	157.04	111.19	1,575.69	1,686.89	1,529.85	12,774.80	206.73	380.73

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Exhibit 3.5.17 21 Yr. 21 Yr. Cumulative Cash Flow Projection Graph \$MM- Company: Roche - Aposecretase (2014-2032)

By: Kali Jelen



Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Fourteenth Edition. Cengage. Manson, OH. CD-ROM. 2013.

Environmental Threats and Opportunities Profile Using TIPSEEECS

By: Alexander Anderson

Introduction

By: Alexander Anderson

An environmental scan is one of the best tools to analyze and identify the impact of both internal and external Threats and Opportunities. The Environmental Threats and Opportunities Profile (ETOP) uses a model that is made up of nine different factors. These include Technology, International, Political, Social, Ecological, Energy, Economic, Competition, and Spirit/Ethics/Spirituality (TIPSEEECS).⁴² In the TIPSEEECS model the impact of each of the factors is then ranked. If a factor is considered to be a Threat it is valued with a negative number ranging from -5 (very strong) to -1 (very weak). If the factor is considered an Opportunity it is given a positive number ranging from 1 (very weak) to 5 (very strong). In addition, the importance associated with each factor is ranked from 1 (unimportant) to 10 (very important).⁴³ The impact and importance of each factor are then multiplied together to produce an ETOP Value to help assess how much factor effects the organization.

Technology

By: Alexander Anderson

When looking at the role of Technology in relation to Alzheimer's disease it is important to note the crucial role of the biotechnology industry along with the pharmaceutical industry.

Biotechnology is the application of science and technology to living organisms.⁴⁴ The importance of the biotechnology industry has led to pharmaceutical companies acquiring biotechnology companies, due to the benefits of developing treatments for disease with a combined effort. Roche recently agreed in August to pay \$8.3B to acquire InterMune, a

California biotech firm that has yet to turn a profit on a new drug to treat a deadly lung disease.⁴⁵ Protein-related technologies are deployed specifically for research and development of therapeutic proteins. These therapeutic proteins are the most important group of biotechnological currently in use. Roche owns and develops cutting edge protein-engineering technologies as well as world-class manufacturing processes and facilities.⁴⁶ One such protein is Brain Shuttle, a technology that Roche developed to increase penetration of large molecules such as antibodies into the brain.⁴⁷

Within the biotechnology industry there is a high level of proprietary knowledge. Due to the high levels of technology required within the industry for specialist technologies, buildings, and equipment associated with the cost of research, new biotechnology companies tend to require a large amount of capital, as they are known for long start up periods with little profit and high fixed costs.⁴⁸ This creates barriers to entry for new companies. As a result, Technology is considered to be a large opportunity within the industry as developing technologies and new research leads to advances in the understanding of disease and prevention.

International

By: Alexander Anderson

Alzheimer's disease is a global challenge. It is the most common form of dementia and can destroy memory and thinking skills as the condition progresses. Currently there are 44 million people with dementia worldwide; thirty-five million of them are suffering from Alzheimer's. Diagnoses are on the rise with 76 million people expected to be living with dementia by 2030. Global collaboration is needed to transform Alzheimer's disease research and treatment.⁴⁹

Politics

By: Alexander Anderson

The Biotechnology Industry is effected by politics via the regulations set by governing bodies. Regulations have become stricter, especially in the medical field, requiring lengthy and costly clinical trials to prove product effectiveness and safeness. The regulations are initiated by the Food and Drug Administration (FDA). The FDA's goal is to protect and promote the health of the nation by regulating the drugs on the market. This acts as a threat to the industry as regulations have become stricter and the time required for FDA approvals have increased as well. In 2009, the FDA implemented a series of reforms that included stricter monitoring of drug adverse events, more funding for the agency, stronger ability to force product recalls, and more scientific expertise within the agency. Thus, the FDA has become more reluctant to approve a high amount of drugs to be released on the market.

President Obama has signed an executive order that lifts the restrictions on stem cell research funding. Stem cell research can play a key role in the development of new treatments, as it allows for studies in genetic patterns.⁵⁰ However, there are many ethical implications as related to stem cell research, which can make Biotechnology companies hesitant over experimenting to discover new developments.

Social

By: Alexander Anderson

The population of baby boomers, those considered to be a part of the shockwave of babies born after World War II, are growing older and becoming part of the elderly population. As a result they tend to be in high demand for new treatments for disease. Alzheimer's disease is the most common form of dementia and can destroy the memory and thinking skills as the condition

progresses. Currently there are forty-four million people with dementia worldwide; thirty-five million of them are suffering from Alzheimer's. Diagnoses are on the rise with seventy-six million people expected to be living with dementia by 2030. Collaboration is needed to transform Alzheimer's disease research and treatment to find a way to prevent this devastating disease.

Ecology

By: Alexander Anderson

The ecological factor is another important consideration when it comes to expanding into a new market. Although there is not any evidence that there is a link between the environment and Alzheimer's disease, efforts can still be made for developing sustainable ecological trends. As society faces the harmful influences it has the environment it has the opportunity to make ecological improvements on the processes to reduce a company's ecological footprint. The need to support clean energy, reduce pollution from carbon emissions, conservation, and recycling is crucial for the environment but also helps keep a company sustainable in the long run.⁵¹

Energy

By: Alexander Anderson

Similar to ecology, currently there is no evidence that the energy factor does not play a direct role in Alzheimer's disease. Despite this, energy is also an important factor to consider when expanding into a new market. Parallel to the mentality that a company wants to consider the environment in relation to its processes, a company also needs to consider how much energy it is using and where that energy is coming from. If fossil fuels are being used to provide energy the environment will suffer. On the other hand if hydro power, wind, or solar power are used there is a limitless amount of energy available with a minimal environmental impact.⁵²

Economics

By: Alexander Anderson

Roche's sales in the Central Nervous System segment amounted to approximately \$865MM for 2013, about a 6% reduction from 2012. It accounts for only 1.6% of Roche's total 2013 sales of \$52.5B. At the same time, the Central Nervous System market segment is growing at a rapid rate, between 2012 and 2013 total sales increased by 5.75% to \$191B. As the Central Nervous System market segment is the second largest in the Pharmaceutical Industry Roche has an opportunity to regain market share by developing a drug for Alzheimer's disease. Alzheimer's already affects 35 million people across the globe and there are currently no effective treatment options. As people live longer thanks to modern medicine more people will be diagnosed with Alzheimer's.

Competition

By: Alexander Anderson

Many competitors are reducing the funds for CNS research and development. This creates a great opportunity to pursue a more effective Alzheimer's treatment with little to no competition currently in that market. With Aposecretase being the first drug of its type on the market, it possesses the ability to gradually generate high monetary sales; however, other companies will most likely begin to develop similar treatments soon thereafter.

Patent expirations of drugs also pose as a threat, as it is an opportunity for competitors to take over market share. This is why, new developments in Research and Development are a necessary part of the industry. Aposecretase would currently have no competitors in the market because there is no other treatment of its kind on the market. Once released developments will need to continue to ensure a competitive edge on other companies that would like to take over.

Competition definitely presents a threat to Roche but it can be managed with proper scanning of the industry.

Spirit/Ethics/Spirituality

By: Alexander Anderson

The Biotechnology Industry can be controversial as people struggle with concerns related to Spirit, Ethics, and Spirituality. Though President Obama overturned President Bush's policy for limitation on stem cell research funding, other policies need to be developed to protect human interest and other ethical concerns. Eventually Alzheimer's leads to death not from being sick directly but usually from malnourishment as those with it eventually struggle to even swallow food. Add the fact that these people are not even themselves anymore because they have forgotten everything that makes them who they are. As such the argument can be made that to not peruse a treatment is just as bad as any tests that may need to be performed. Every action and decision has both Pro's and Con's associated with the outcome. However, if the Pro's outweigh the Con's it will greatly benefit society, but if it puts certain ethical values into question then the strategy must be reevaluated.

Exhibit 3.5 18: Roche ETOP Graph 2014

By: Alexander Anderson

Worksheet 1.2

Strategy #3: Aposecretase

V.Seshan

EXHIBIT 16.12 - Environmental Threats & Opportunities Profile (ETOP) Alzheimer's Disease CNS Market Segment

Factors	Impact of Factor	Importance of Factor	Environmental Threat/Opportunity	Rank
Competition	-3	8	-24	1
Politics	-2	5	-10	2
Spirit / Ethics	-4	4	8	3
Ecology	1	3	3	4
Energy	1	2	2	5
International	2	5	10	6
Social	3	7	21	7
Economics	4	8	32	8
Technology	5	10	50	9
Total ETOP Score				
=			73	

Impact is ranked from -5 (strongly negative) to +5 (strongly positive).

Importance is ranked from 1 (unimportant) to 10 (very important).

Comments: The Central Nervous System market segment is the second largest in the pharmaceutical industry and grew by 5.75% between 2012 and 2013. At the same time it only accounts for 1.6% of Roche's total 2013 sales. Roche has an opportunity to regain market share by developing a drug for Alzheimer's disease. Alzheimer's already affects 35 million people and there are currently no effective treatment options. As people live longer due to modern medicine more people will be diagnosed with Alzheimer's. At the same time, Roche needs to continually improve to stay ahead of its competition as well as satisfy governing bodies who are concerned for the safety of the public.

Source:

Rowe, Alan J., Mson, Richard O., Dickel, Karl E., Mann, Richard B., Mockler, Robert J., Strategic Management- A Methodological Approach. 4th Ed. 1999, Reading, MA: Addison- Wesley. Page 115. TIPSEECs Model Copyright By: Dr. V. Seshan

Mann, Rowe, and Seshan, Strategy for the 21st Century, Pages 75-81, IBT Global, Edition 5.5, 2011

Stakeholder Analysis

By: Alexander Anderson

Introduction

By: Alexander Anderson

Stakeholders are individuals or groups that can affect the organization or those who are affected by the organization's actions. They all have stakes in the organization and each stakeholder is counting on the organization to achieve its goals. Because all stakeholders have a claim on the company, it is up to the managers and executives to further the success of the organization.⁵³

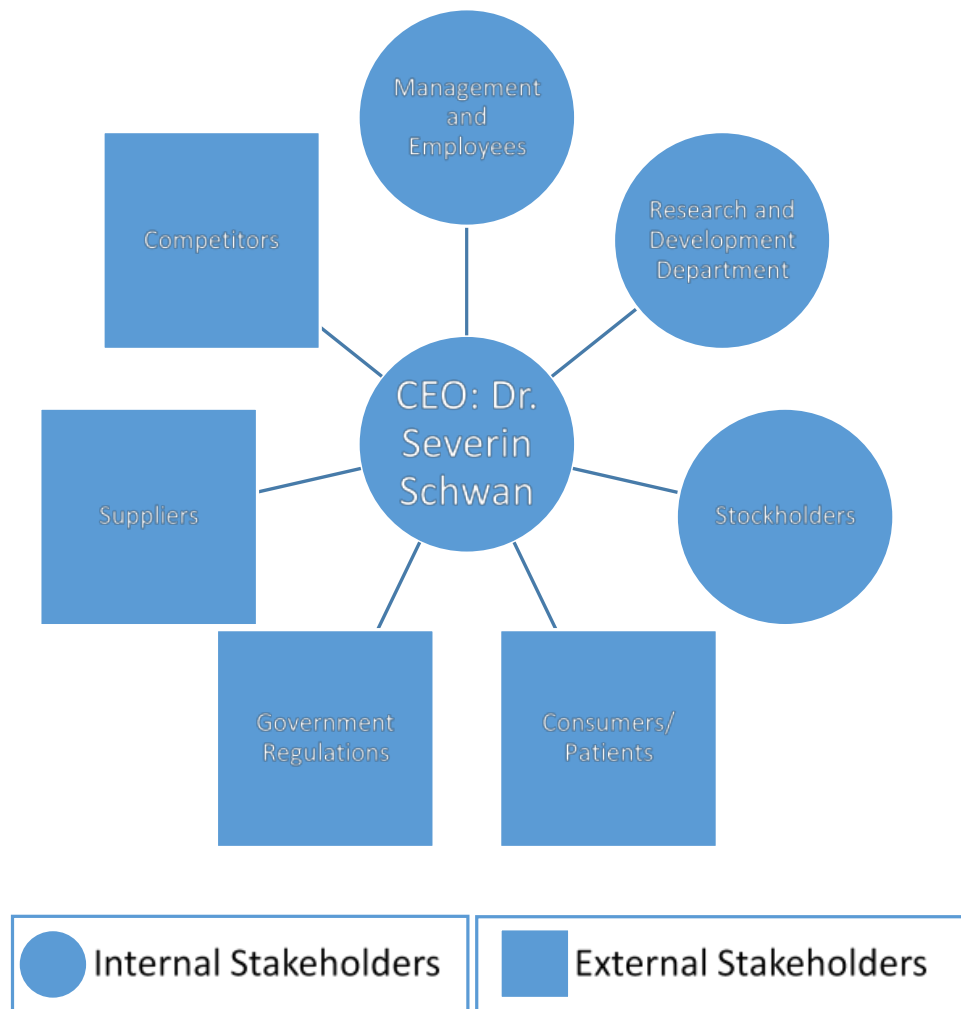
Performing a Stakeholder Analysis allows executives to determine who their stakeholders are and allows them to build mutual interactive relationships with stakeholders in order to achieve their goals and improve upon the organization. In order to do this, the managers of the company must evaluate the importance of their goals and minimize problems that may arise as a result.⁵⁴

A Stakeholder Analysis gives a visual representation on who the Internal Stakeholders and External Stakeholders are.⁵⁵

A Stakeholder Analysis is performed by identifying the stakeholders and evaluating their association to the company. This allows managers to analyze the opportunities and threats presented with each stakeholder. The analysis assigns assumptions to given stakeholders and looks at the supporting and resisting forces these stakeholders can have on the organization. Executives evaluate these factors and organize strategies that will best serve the organization.⁵⁶

Exhibit 3.5 19: Roche Steerer Model 2014

By: Alexander Anderson



Source:

Rowe, Alan J., Mason, Richard O., Dickel, Karl E., Mann, Richard B., and Mockler, Robert J. "Stakeholder Analysis." Strategic Management - A Methodological Approach. Fourth Edition. Addison-Wesley. New York. Page 141. 1999.

Seshan, V. Ph.D. "Stakeholder Analysis." Strategic Management Financial Analysis and Cash Flow. Thirteenth Edition. Thomson. Mason, OH. CD-ROM. 2012.

Internal Stakeholders

By: Alexander Anderson

Management and Employees

By: Alexander Anderson

The person responsible for pursuing the long-term interests of the company and its stakeholders is the Chief Executive Officer. As such the CEO is critical to the company's success. Duties range from engaging in strategies that contribute to the organization's overall business growth as well as selecting management to monitor that growth. The CEO of Roche since 2008 is Dr. Severin Schwan.⁵⁷ Schwan brings a relentless drive for innovation and a passion for personalized healthcare. He joined Roche in 1993 as a trainee and has stayed with the company ever since. He is fascinated with Roche because "we can literally save millions of lives and improve the quality of life of millions of patients and their families".⁵⁸ Schwan earned his Doctorate in Law at University of Innsbruck in Belgium. He has been a member of the Board of Directors of Roche Holding Ltd, the European Round Table of Industrialists, the Board of Directors of Credit Suisse Group, and the International Business Leaders Advisory Council for the Mayor of Shanghai. He says, "Proud as we are of our past and present achievements, what really excites us, however, is the future." The pursuit of a cure for Alzheimer's disease lines right up with what Schwan has been doing and wants to do in the future.

Roche believes that employees who are engaged are key to delivering the highest standards and the greatest levels of innovation. Three values sustain the culture and further the quest to help people achieve good health and longevity: integrity, courage and passion.⁵⁹ Roche aspires to embody these values in everything it does. All of this points to the fact that both the employees and their managers will accomplish the strategy of finding a cure for Alzheimer's disease.

Research and Development Department

By: Alexander Anderson

Roche has a strong corporate culture where employees are engaged, diversified, and balanced. Currently there are more than 18,000 employees working on research and development to deliver medical innovations.⁶⁰ The scientists at Roche are passionate about helping people combat the world's hardest-to-treat diseases. To ensure a strong pipeline there is a network of Research and Development centers around the world. In addition to the R&D centers, Roche makes clinical study reports available to qualified researchers for further scientific study. This worldwide partnering expands innovation network in the area of in vitro diagnostics.⁶¹

Roche has positioned itself to fit the treatment of the patients by working in both Pharmaceuticals and Diagnostics. It believes that finding innovative solutions for serious, currently unsolved medical problems is what a healthcare company is all about. Roche employees strive to create clinically differentiated drugs and diagnostic tests to enable tangible improvements in the health, quality of life and survival of patients. These R&D mentalities are exactly what is needed when trying to come up with a solution Alzheimer's disease.⁶²

Stockholders

By: Alexander Anderson

Shareholders are important Stakeholders in any project a company develops. The goal of every corporation should be to maximize shareholder wealth. A shareholder can be defined as a "person, company, or other institution that owns at least one share in a company". Also referred to as a Stockholder, a Shareholder has the potential to profit if the company has financial success, however also has the potential to experience losses if the company performs poorly.⁶³

The success of Aposecretase for Roche has the opportunity to provide profit for Shareholders

and keep them invested within the company. Stockholders are important to Roche's development of Aposecretase because it is one of the means of raising capital for further Research and Development. Aposecretase gives Roche the chance to dominate an untapped market by helping fight Alzheimer's disease.

External Stakeholders

By: Alexander Anderson

Consumers/Patients

By: Alexander Anderson

Customers' needs and wants are vital to Roche's financial success, which makes them Roche's most important stakeholder. Roche is urgently trying to deliver patients medical solutions right now while it develops innovations for what they need next in the future. Customers are the biggest External Stakeholders as they generate sales and thus profit for the corporation. As a new drug with benefits exclusive to itself, Aposecretase will come at a higher cost of production. This cost will be passed down as a higher selling price once it is released into the market. The high cost will be determined through the level of research involved, the technologies required for development, resources used, and other additional costs. Despite the high cost of treatment, patients will likely want to purchase Aposecretase and have the means to do so given their mature age and desire to prevent any of their conditions from worsening.

Government Regulation

By: Alexander Anderson

The U.S. Food and Drug Administration (FDA) has a large stake in determining Roche's success as it has the authorization to approve or reject Roche's products. It is the FDA's duty to protect people by assuring the safety, efficacy, and security of drugs, biological products, and medical

devices.⁶⁴ What makes the FDA even more vital to Roche's success is that it has the power to promote public health by speeding up the process in which medical products are approved. It is also the FDA's responsibility to make sure the public has enough available knowledge in understanding the drugs in which they are taking to improve their health.⁶⁵ Complying with FDA standards is crucial to the development process, as Roche does not want its products to have adverse effects on customers.

Suppliers

By: Alexander Anderson

Roche makes their foals of integrity and transparency integral to their business. Their supplier objectives are aligned with the Roche Group strategy as include key performance indicators and targets. Remaining in alignment with their mission, Roche relies on a large and diverse supply network to bring innovative medicines and diagnostics to people who need them.⁶⁶ Roche established procurement procedures and take steps to make sure that their partners adhere to the same principles. At the same time Roche invites its suppliers to work with them on improving the sustainability of the supply chain. All of this is in the name of innovation and performance and risk management.⁶⁷

Competitors

By: Alexander Anderson

Many competitors are reducing the funds for CNS research and development. As mentioned above, this creates a great opportunity to pursue a more effective Alzheimer's treatment with little to no competition currently in that market. While Aposecretase has great potential to grow and generate high monetary sales due to its position in the market, once other companies see the success they will begin to develop similar treatments and follow suit. This is why, new

developments in Research and Development are a necessity. Aposecretase would currently have no competitors in the market because there is no other treatment of its kind on the market. Once released developments will need to continue to ensure a competitive edge on other companies that begin to move into the same market segment. Competition definitely presents a threat to Roche but it can be managed to effect Roche in a lesser way for a longer period of time.

Exhibit 3.5 20: Roche Internal Stakeholder Assumption Graph 2014 for Aposecretase, CNS Segment Strategy

By: Alexander Anderson

Stakeholders	Major Assumptions	Importance	Certainty
1. Management and Employees	Supporting: a. CEO has a relentless drive for innovation	7	9
	b. Engaged employees will deliver the high standards and levels of innovation	4	4
	Resisting: a. Large failure in development is a waste of capitol allocation	5	4
	b. Poor management allocated to research	3	2
2. Research and Development Department	Supporting: a. Competitive R&D department has led to Roche being one of the greatest	5	7
	b. Partners are on the same page as Roche	7	5
	Resisting: a. Untapped market where little is known about Alzheimer's disease	8	7
	b. High costs associated with new research	8	8
3. Stockholders	Supporting: a. Acquisition of other companies	7	8
	b. Leading biotechnology and pharmaceutical company	7	5
	Resisting: a. Entering new market could lead to losses	8	5
	b. Investors pull out due to risk	4	2

Source:

Rowe, Alan J., Mason, Richard O., Dickel, Karl E., Mann, Richard B., and Mockler, Robert J. "Stakeholder Analysis." Strategic Management - A Methodological Approach. Fourth Edition. Addison-Wesley. New York. Page 141. 1999.

Seshan, V. Ph.D. "Stakeholder Analysis." Strategic Management Financial Analysis and Cash Flow. Thirteenth Edition. Thomson. Mason, OH. CD-ROM. 2012.

**Exhibit 3.5 21: Roche External Stakeholder Assumption Graph 2014 for Aposecretase,
CNS Segment Strategy**

By: Alexander Anderson

Stakeholders	Major Assumptions	Importance	Certainty
4. Consumers / Patients	Supporting: a. Supporting Alzheimer's patients will increase patient reach	7	2
	b. R&D is leading to better medicines and treatments	8	8
	Resisting: a. Unwanted side effects	8	2
	b. Drug is not effective	9	2
5. Government Regulation	Supporting: a. Value promotion of public health	5	5
	b. Ensure products are safe and reliable	8	7
	Resisting: a. Long process to get drug on the market	6	9
	b. Support from the government could fade	3	2
6. Suppliers	Supporting: a. Supportive suppliers	7	7
	b. Not reliant on any one supplier	8	7
	Resisting: a. Difficult to keep suppliers standards high	4	5
	b. Suppliers may leave or need to be cut	4	6
7. Competitors	Supporting: a. Unrivaled treatment	9	9
	b. Acquisitions and no competition	8	8
	Resisting: a. Generics will be looking to take over	8	9
	b. Will not get the benefit of others working on the same thing	4	3

Source:

Rowe, Alan J., Mason, Richard O., Dickel, Karl E., Mann, Richard B., and Mockler, Robert J. "Stakeholder Analysis." Strategic Management - A Methodological Approach. Fourth Edition. Addison-Wesley. New York. Page 141. 1999.

Seshan, V. Ph.D. "Stakeholder Analysis." Strategic Management Financial Analysis and Cash Flow. Thirteenth Edition. Thomson. Mason, OH. CD-ROM. 2012.

Exhibit 3.5 22: Roche Force Field Analysis 2014 for Aposecretase, CNS Segment Strategy

By: Alexander Anderson

Supporting										Resisting									
	9	8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8	9	
Roche Internal										Stakeholders 2013									
1Sa																			1Ra
1Sb																			1Rb
2Sa																			2Ra
2Sb																			2Rb
3Sa																			3Ra
3Sb																			3Rb
Roche External										Stakeholders 2013									
4Sa																			4Ra
4Sb																			4Rb
5Sa																			5Ra
5Sb																			5Rb
6Sa																			6Ra
6Sb																			6Rb
7Sa																			7Ra
7Sb																			7Rb

Stakeholder	Supporting a	Supporting b	Resisting a	Resisting b
Management & Employees	1Sa	1Sb	1Ra	1Rb
Research & Development	2Sa	2Sb	2Ra	2Rb
Stockholders	3Sa	3Sb	3Ra	3Rb
Consumer / Patients	4Sa	4Sb	4Ra	4Rb
Government Regulation	5Sa	5Sb	5Ra	5Rb
Suppliers	6Sa	6Sb	6Ra	6Rb
Competitors	7Sa	7Sb	7Ra	7Rb

Source:

Rowe, Alan J., Mason, Richard O., Dickel, Karl E., Mann, Richard B., and Mockler, Robert J. "Stakeholder Analysis." Strategic Management - A Methodological Approach. Fourth Edition. Addison-Wesley. New York. Page 141. 1999.

Seshan, V. Ph.D. "Stakeholder Analysis." Strategic Management Financial Analysis and Cash Flow. Thirteenth Edition. Thomson. Mason, OH. CD-ROM. 2012.

Exhibit 3.5 23: Roche Stakeholders Assumption Matrix 2014 for Aposecretase, CNS Segment Strategy

By: Alexander Anderson

Certain 9 Knowledge About Assumptions Uncertain 0							1Sa	7Ra	7Sa
							3Sa	2Rb, 4Sb, 7Sb	
				2Sa			6Sa	2Ra, 5Rb, 6Sb	
			6Rb						
			6Ra	5Sa			2Sb, 3Sb	3Ra	
			1Sb	1Ra					
			7Rb						
		1Rb	3Rb				4Sa	4Ra	4Rb
<div style="display: flex; justify-content: space-between; width: 100%;"> 0 Unimportant Impact of Strategy 9 Important </div>									

Stakeholder	Supporting a	Supporting b	Resisting a	Resisting b
Management & Employees	1Sa	1Sb	1Ra	1Rb
Research & Development	2Sa	2Sb	2Ra	2Rb
Stockholders	3Sa	3Sb	3Ra	3Rb
Consumer / Patients	4Sa	4Sb	4Ra	4Rb
Government Regulation	5Sa	5Sb	5Ra	5Rb
Suppliers	6Sa	6Sb	6Ra	6Rb
Competitors	7Sa	7Sb	7Ra	7Rb

Source:

Rowe, Alan J., Mason, Richard O., Dickel, Karl E., Mann, Richard B., and Mockler, Robert J. "Stakeholder Analysis." Strategic Management - A Methodological Approach. Fourth Edition. Addison-Wesley. New York. Page 141. 1999.

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Strategic Position and Action Evaluation (SPACE) Analysis

By: Kali Jelen

Introduction

By: Kali Jelen

A Strategic Position and Action Evaluation Analysis (SPACE) is a market analysis tool used to determine whether Aggressive, Conservative, Defensive, or Competitive strategy is best for a given market.⁶⁸ This is determined by plotting a graphical representation of a given strategy's environmental stability, industry strength, competitive advantage, and financial strength. The Y axis holds the environmental stability and financial strength indicators, while the x axis compares the competitive advantage and industry strength indicators. Overall, SPACE analysis is visual representation of an undertaking's strategic position in a market.⁶⁹

Environmental Stability

By: Kali Jelen

Environmental stability factors include technology changes, rate of inflation, demand variability, price range of competing products, and barriers to entry, competitive pressures, price elasticity of demand, and pressures from substitute products.⁷⁰ This section helps to establish where Roche stands in the pharmaceutical industry and specifically in the central nervous system market. The pharmaceutical market is well-established and therefore not exceptionally likely to change. Major factors to note are the high scores for competition and the low score for technology. The pharmaceutical industry is characterized by cut throat competition and a high rate of technology turn over. Part of the reason for the large research and development expenditures in this field is due to the need to stay relevant against the competition in an ever changing technological market place. The environment of the CNS market segment is fairly stable despite the high technology turnover rate and the intense competition.

Industry Strength

By: Kali Jelen

Industry Strength factors include growth potential, profit potential, financial stability, technological knowhow, resource utilization, capital intensity, ease of entry into market, and productivity utilization. This segment of the SPACE Analysis indicates whether or not the industry will remain the same or change over time and directly affects sales and thus profits.⁷¹

Industry strength indicates how Roche can expect to perform in this specific portion of the CNS market segment. Factors to note are the high ease of entry and capital intensity scores. The pharmaceutical industry in general and the CNS market segment in particular require a large amount of capital in the form of research and development dollars which create a very difficult barrier to entry. Roche, with its extensive war chest, is able to scale the high cost of entry in to the CNS market without too much difficulty, however this barrier could potentially block out other, smaller competitors, or even some larger competitors who would choose to focus their R&D dollars elsewhere.

Competitive Advantage

By: Kali Jelen

The factors influencing competitive advantage are market share, product quality, product life cycle, product replacement cycle, customer loyalty, competition's capacity utilization, technological knowhow, vertical integration, and speed of new product introductions. This section describes how Roche can expect its product to do against its competitors in the pharmaceutical industry.⁷² Additionally it also indicated the likelihood of Roche maintaining its competitive advantage in the future. Aposecretase will be the first drug to address the symptoms of Alzheimer's disease, rather than the symptoms. At first this will give Roche a great advantage over its competitors. However, Roche is not the only company working on a treatment of this type. Roche can expect to have to compete against strong products from rival pharmaceutical companies. Factors to pay attention to in this section are the low speed of new product introductions and the low customer loyalty scores. It is difficult to get new products to market in the pharmaceutical industry due to government regulations requiring extensive clinical trials and testing. While this is burdensome for Roche initially, in the long run it will protect their product

as every month a competitor is forced to spend in the clinical trial phase is another month Roche's drug can continue its' patent life without direct competition. Additionally, in the pharmaceutical industry customers are assumed to have little to no brand loyalty. Instead, factors such as price, quality, and effectiveness of the product take precedence.

Financial Strength

By: Kali Jelen

Financial Strength factors are return on investment, leverage, liquidity, capital required vs. capital available, cash flow, ease of exit from market, risk involved in business, *economies of scale* and expenditure, and inventory turnover. This section indicates how well this project is doing using standard financial measures.⁷³ While overall the industry is relatively financially stable every new project is a fairly large gamble. Roche is one of the most financial stable companies in the industry. Factors to particularly note are the high score for capital available vs capital required and the low score for ease of exit from market. Roche's strong financial position allows means that the Aposecretase project will be well funded and supported. The capital allocation of 4.61 billion dollars will more than meet the required investment for the development and launch of this new project. Aposecretase will by no means be underfunded. Another factor to note is the extremely low score for exit to market. It will be very difficult and costly to exit the CNS market. Equipment and personnel are too specialized to reallocate or sell off. Therefore Roche must be certain if undertaking this project to keep up research and development expenditures to ensure the longevity of its product. Roche must be ready to pivot their product to address increased threat from competition.

Exhibit 3.5.24 Roche Strategic Position and Action Evaluation for Aposecretase Environmental Stability 2014

By: Kali Jelen

Factors Determining Environmental Stability:										R	C	E
Technological changes	Many	0	1	2	3	4	5	6	Few	9	0.6	5.4
Rate of inflation	High	0	1	2	3	4	5	6	Low	7	0.8	5.6
Demand variability	Large	0	1	2	3	4	5	6	Small	6	0.7	4.2
Price Range of competing products	Wide	0	1	2	3	4	5	6	Narrow	7	0.6	4.2
Barriers to entry into market	Few	0	1	2	3	4	5	6	Many	8	0.9	7.2
Competitive pressure/rivalry	High	0	1	2	3	4	5	6	Low	9	0.5	4.5
Price elasticity of demand	Elastic	0	1	2	3	4	5	6	Inelastic	5	0.7	3.5
Pressure from substitute products	High	0	1	2	3	4	5	6	Low	9	0.4	3.6
										Total:		38.2

Average -6 = -4.375

R: Relative Importance of Factor

C: Chance of sustaining importance

E: Combined Effect of Factor

Critical Factors: The high barrier to entry in to this market is driven by the rapid rate at which technology evolves.

Comments: Roche should utilize its past research efforts and currently existing facilities to minimize the barriers to entry for Aposecretase.

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Eleventh Edition. Cengage. Mason, OH. CD-ROM. 2010.

Exhibit 3.5.25 Roche Strategic Position and Action Evaluation for Aposecretase Industry Strength 2014

By: Kali Jelen

Factors Determining Industry Strength:										R	C	E
Growth Potential	Low	0	1	2	3	4	5	6	High	7	0.6	4.2
Profit Potential	Low	0	1	2	3	4	5	6	High	8	0.8	6.4
Financial Stability	Low	0	1	2	3	4	5	6	High	9	0.9	8.1
Technological know-how	Simple	0	1	2	3	4	5	6	Complex	9	0.9	8.1
Resource utilization	Inefficient	0	1	2	3	4	5	6	Efficient	7	0.6	4.2
Capital intensity	Low	0	1	2	3	4	5	6	High	6	0.7	4.2
Ease of entry into market	Easy	0	1	2	3	4	5	6	Difficult	9	0.8	7.2
Productivity, capacity, utilization	Low	0	1	2	3	4	5	6	High	5	0.6	3
Other: Manufacturers' bargaining power	Low	0	1	2	3	4	5	6	High	3	0.4	1.2
										Total:		46.6

Average= 4.22

R: Relative Importance of Factor

C: Chance of sustaining importance

E: Combined Effect of Factor

Critical Factors: The pharmaceutical industry is incredibly strong with massive profit potential. However, it is very difficult to enter the market due to the massive amount of capital required and to efficiently utilize resources.

Comments: Aposecretase will be Roche's first Alzheimer's medication. The cost to enter the market will be very high and the Aposecretase project will only be successful if Roche's maintains or increases its current financial stability and willingness to invest.

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Eleventh Edition. Cengage. Mason, OH. CD-ROM. 2010.

Exhibit 3.5.26 Roche Strategic Position and Action Evaluation for Aposecretase Competitive Advantage 2014

By: Kali Jelen

Factors Determining Competitive Advantage:										R	C	E
Market share	Small	0	1	2	3	4	5	6	Large	7	0.6	4.2
Product quality	Interior	0	1	2	3	4	5	6	Superior	9	0.9	8.1
Product life cycle	Late	0	1	2	3	4	5	6	Early	6	0.5	3
Product replacement cycle	Variable	0	1	2	3	4	5	6	Fixed	5	0.4	2
Customer loyalty	Low	0	1	2	3	4	5	6	High	3	0.8	2.4
Competition's capacity utilization	Low	0	1	2	3	4	5	6	High	5	0.7	3.5
Technological know-how	Low	0	1	2	3	4	5	6	High	9	0.9	8.1
Vertical integration	Low	0	1	2	3	4	5	6	High	3	0.3	0.9
Speed of new product introductions	Slow	0	1	2	3	4	5	6	Fast	6	0.9	5.4
										Total:		37.6

Average -6 = -3

R: Relative Importance of Factor

C: Chance of sustaining importance

E: Combined Effect of Factor

Critical Factors: Customer loyalty is virtually non-existent in the pharmaceutical industry. The only important factors are the cost and effectiveness of products. Furthermore the speed of new product introductions is incredibly slow due to extensive governmental regulations requiring multiple rounds of clinical trials and review.

Comments: Roche should expect to have to wait an period of time before releasing Aposecretase to the public in order to satisfy FDA regulations. Furthermore Roche should be extra wary of being out engineer by its competitors, as it will never be able to maintain customers based on brand loyalty.

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Eleventh Edition. Cengage. Mason, OH. CD-ROM. 2010.

Exhibit 3.5.27 Roche Strategic Position and Action Evaluation for Aposecretase Financial Strength 2014

By: Kali Jelen

Factors Determining Financial Strength:										R	C	E
Return on investment	Low	0	1	2	3	4	5	6	High	9	0.9	8.
Leverage	Imbalanced	0	1	2	3	4	5	6	Balanced	7	0.7	4.
Liquidity	Imbalanced	0	1	2	3	4	5	6	Solid	6	0.7	4.
Capital required versus capital available	High	0	1	2	3	4	5	6	Low	9	0.8	7.
Cash flow	Low	0	1	2	3	4	5	6	High	8	0.9	7.
Ease of exit from market	Difficult	0	1	2	3	4	5	6	Easy	3	0.7	2.
Risk involved in business	Much	0	1	2	3	4	5	6	Little	8	0.9	7.
Inventory turnover	Slow	0	1	2	3	4	5	6	Fast	4	0.2	0.
Economies of scale and experience	Low	0	1	2	3	4	5	6	High	7	0.6	4.
										Total:		45.

Average = 3.33

R: Relative Importance of Factor

C: Chance of sustaining importance

E: Combined Effect of Factor

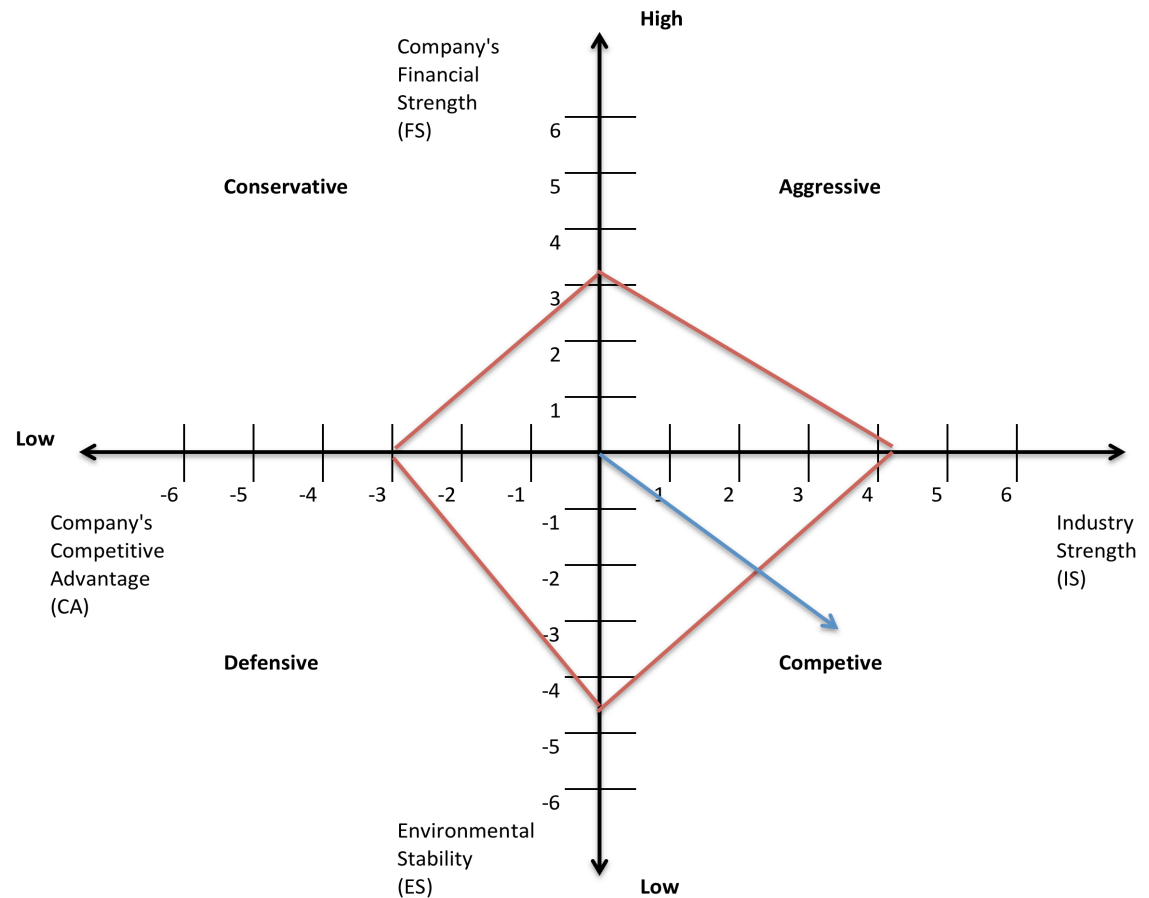
Critical Factors: It is incredibly difficult to exit this market due to the extremely specialized equipment and personnel.

Comments: Roche must be sure to maintain high R&D expenditures to ensure that a new patent can be secured when Aposecretase's patent expires in 2034.

Source: Seshan, V. Ph.D. Strategic Management Financial Analysis and Cash Flow. Eleventh Edition. Cengage. Mason, OH. CD-ROM. 2010.

Exhibit 3.5.28 Roche Strategic Position and Action Evaluation for Aposecretase Acti Evaluation Graph 2014

By: Kali Jelen



Comments: According to the SPACE analysis Roche should use a competitive approach to implement the Aposecretase strategy. The Alzheimer's market is primed for a new leader. V superior technology and strong capital support Roche can easily gain a sizeable share of the market.

Source:

Mann, Richard B. and Seshan, V. Strategy for the 21st Century, Sixth Edition, IBT Global, 2012.

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